

**28-35-135a. Definitions.** As used in these regulations, each of the following terms shall have the meaning specified in this regulation:

(a) "A<sub>1</sub>" means the maximum activity of special form radioactive material permitted in a type A package.

(b) "A<sub>2</sub>" means the maximum activity of radioactive material, other than special form radioactive material, permitted in a type A package. These values are listed in or may be derived as specified in 10 C.F.R. part 71, appendix A, which is adopted by reference in K.A.R. 28-35-221b.

(c) "Absorbed dose" means the energy imparted to matter by ionizing radiation per unit mass of irradiated material at the place of interest. The units of absorbed dose are the rad and the gray (Gy).

(d) "Absorbed dose rate" means the absorbed dose per unit of time or, for linear accelerators, the dose monitor unit per unit of time.

(e) "Accelerator-produced material" means any material made radioactive by exposing it in a particle accelerator.

(f) "Accessible surface" means the surface of equipment or of an equipment part that can be easily or accidentally touched by persons without the use of a tool.

(g) "Accident" means an unintended event, including an operating error, equipment failure, and other mishap, that could result in either of the following:

(1) A dose in excess of regulatory limits on site or for the public; or

(2) consequences or potential consequences that cannot be ignored from the point of view of protection or safety, including an actual or potential substantial degradation of the level of

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protection or safety of the facility or the release of radioactive material in sufficient quantity to warrant consideration of protective actions.

(h) "Act" means the "nuclear energy development and radiation control act," K.S.A. 48-1601 et seq., and amendments thereto.

(i) "Activity" means the rate of disintegration, transformation, or decay of radioactive material. Activity is expressed in the SI unit of becquerel (Bq) or in the special unit of curie (Ci), or the multiples of either unit.

(j) "Added filter" means the filter added to the inherent filtration.

(k) "Address of use" means the building or buildings that are identified on the license and each location where radioactive material could be produced, prepared, received, used, or stored.

(l) "Adult" means an individual who is 18 or more years of age.

(m) "Aggregated" means accessible by the breach of a single physical barrier that could allow access to radioactive material in any form, including any devices that contain the radioactive material, when the total activity equals or exceeds a category 2 quantity of radioactive material.

(~~n~~)(1) "Agreement state" means any state with which the nuclear regulatory commission (~~NRC~~) enters, or has entered, into an effective agreement pursuant to subsection 274b of the atomic energy act of 1954, 68 Stat. 919, as amended.

(2) "Non-agreement state" means any other state.

(~~n~~) (o) "Airborne radioactive area" means the following:

(1) Any room, enclosure, or operating area in which airborne radioactive material exists

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in concentrations in excess of the derived air concentrations (DAC) specified in the department's "appendices to part 4: standards for protection against radiation," effective April 1994, ~~published by the department and~~ which is hereby adopted by reference; or

(2) any room, enclosure, or operating area in which airborne radioactive material exists in concentrations such that an individual present in the area without respiratory protective equipment could exceed, during the hours an individual is present in a week, an intake of 0.6 percent of the ALI or 12 DAC-hours.

~~(p)~~ (p) "Airborne radioactive material" means any radioactive material dispersed in the air in the form of dust, fumes, mists, vapors, or gases.

~~(p)~~ (q) "Air kerma" means the kinetic energy released in air by ionizing radiation. Kerma is determined by dividing  $dE$  by  $dM$ , where  $dE$  is the sum of the initial kinetic energies of all the charged ionizing particles liberated by uncharged ionizing particles in air of mass  $dM$ . The SI unit of air kerma is joule per kilogram, and the special name for the unit of kerma is the gray (Gy).

~~(p)~~ (r) "Alert" means a period during which one of the following could lead to a release of radioactive material that is not expected to require a response by off-site response organizations to protect persons off-site:

- (1) Conditions have arisen that could cause an event.
- (2) An event is in progress.
- (3) An event has occurred.

~~(p)~~ (s) "Aluminum equivalent" means the thickness of type 1100 aluminum alloy that

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affords the same attenuation, under specified conditions, as that of the material in question. The nominal chemical composition of type 1100 aluminum alloy is a minimum of 99.00 percent aluminum and 0.12 percent copper.

~~(s)~~ (t) "Amendment" means any change to a license or registration issued under these regulations.

~~(t)~~ (u) "Analytical X-ray system" means a group of local and remote components utilizing X-rays to determine the elemental composition or to examine the microstructure of materials.

(1) Local components shall include those components that are struck by X-rays, including radiation source housings, port and shutter assemblies, collimators, sample holders, cameras, goniometers, detectors, and shielding.

(2) Remote components may include power supplies, transformers, amplifiers, readout devices, and control panels.

~~(u)~~ (v) "Annual limit on intake" and "ALI" mean the derived limit for the amount of radioactive material taken into the body of an adult worker by inhalation or ingestion in a year. ALI is the smaller value of intake of a given radionuclide in a year by the reference man that would result in a committed effective dose equivalent of 5 rem (0.05 Sv) or a committed dose equivalent of 50 rem (0.5 Sv) to any individual organ or tissue. ALI values for intake by ingestion and by inhalation of selected radionuclides are specified in appendix B, table I, published in "appendices to part 4: standards for protection against radiation," which is adopted by reference in this regulation.

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~~(v)~~ (w) “Annual refresher safety training” means a review conducted or provided by the licensee or registrant for its employees on radiation safety aspects of industrial radiography. The review shall include, at a minimum, any results of internal inspections, new procedures or equipment, new or revised regulations, and accidents or errors that have been observed. The review shall also provide opportunities for employees to ask safety questions.

~~(w)~~ (x) “American national standards institute” and “ANSI” ~~means the American national standards institute~~ mean the organization that provides a framework for fair standards development and quality conformity assessment systems, safeguards the integrity of the standards, and publishes standards documents. The address of ANSI is provided in 10 C.F.R. 34.20(a)(1).

~~(x)~~ (y) “Applicator” means a structure that determines the extent of the treatment field at a given distance from the virtual source.

~~(y)~~ (z) “Area of use” means a portion of a physical structure that has been set aside for the purpose of producing, preparing, receiving, using, or storing radioactive material.

~~(z)~~ (aa) “As low as is reasonably achievable” and “ALARA,” when used to describe exposures to radiation workers, mean that every reasonable effort has been made to maintain exposures to radiation workers as far below the dose limits specified in these regulations as is practical, consistent with the purpose for which the licensed or registered activity is undertaken, taking the following into account:

- (1) The state of technology;
- (2) the economics of improvements in relation to the state of technology;

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(3) the economics of improvements in relation to benefits to public health and safety and to other societal and socioeconomic considerations; and

(4) the economics of improvements in relation to the utilization of nuclear energy and licensed or registered sources of radiation in the public interest.

~~(aa)~~ (bb) “Assembler” means any person engaged in the business of assembling, replacing, or installing one or more components into an X-ray system or subsystem. The term shall include the owner of an X-ray system ~~or~~ and any employee or agent of the owner who assembles components into an X-ray system that is subsequently used to provide professional or commercial services.

(cc) “Associate radiation safety officer” means an individual who meets the requirements specified in 10 C.F.R. 35.50 and 35.59, as adopted in K.A.R. 28-35-264, and is currently approved by the department for the types of use of by-product material for which the individual has been assigned duties and tasks by the radiation safety officer. Each associate radiation safety officer shall obtain one of the following:

(1) A specific medical use license issued by the commission or an agreement state;

(2) a medical use permit issued by the commission; or

(3) a master materials license issued by the commission.

~~(bb)~~ (dd) “Associated equipment” means equipment that is used in conjunction with a radiographic exposure device that makes radiographic exposures and that drives, guides, or comes in contact with the source.

~~(ee)~~ (ee) “Attenuation block” means a block or stack, with dimensions of 20 cm by 20 cm

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by 3.8 cm, made of type 1100 aluminum alloy or other materials having equivalent attenuation.

(dd) (ff) “Authorized user” means an individual who is ~~identified as an authorized user~~ approved by the department and listed on a license issued by the department for the use of radioactive material or an individual who is designated by a registered facility as a user of X-ray machines or accelerators. This term shall not apply to part 6 of these regulations.

(ee) (gg) “Automatic exposure control” means a device that automatically controls one or more technique factors in order to obtain a required quantity of radiation, at one or more preselected locations. (Authorized by K.S.A. 48-1607; implementing K.S.A. 2017 2020 Supp. 48-1603 and K.S.A. 48-1607; effective Dec. 30, 2005; amended July 27, 2007; amended May 4, 2018; amended P-\_\_\_\_\_.)

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**28-35-135c. Definitions.** As used in these regulations, each of the following terms shall have the meaning specified in this regulation:

(a) "Cabinet radiography using radiation machines" means industrial radiography that is conducted in an enclosed, interlocked cabinet that prevents the radiation machine from operating unless all openings are securely closed and that is sufficiently shielded so that every location on the cabinet's exterior meets the conditions for an unrestricted area as specified in K.A.R. 28-35-214a.

(b) "Cabinet X-ray system" means an X-ray system with the X-ray tube installed in an enclosure, called a "cabinet," that is independent from existing architectural structures except the floor on which the cabinet could be placed. The cabinet is intended for the following purposes:

- (1) To contain at least that portion of a material being irradiated;
- (2) to provide radiation attenuation; and
- (3) to exclude personnel from the interior of the cabinet during the generation of X-rays.

This term shall include all X-ray systems designed primarily for the inspection of carry-on baggage at airline, railroad, and bus terminals, and in similar facilities. An X-ray tube that is used within a shielded part of a building, or X-ray equipment that may temporarily or occasionally incorporate portable shielding, shall not be considered a cabinet X-ray system.

(c) "Calendar quarter" means at least 12 but not more than 14 consecutive weeks. The first calendar quarter of each year shall begin in January. Subsequent calendar quarters shall be arranged so that no day is included in more than one calendar quarter and no day in any one year is omitted from inclusion within a calendar quarter. A licensee or registrant shall not change the method of determining and observing calendar quarters for purposes of these regulations except

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at the beginning of a calendar year.

(d) "Calibration" means the determination of either of the following:

(1) The response or reading of an instrument relative to a series of known radiation values over the range of the instrument; or

(2) the strength of a source of radiation relative to a standard.

(e) "Camera" means a radiographic exposure device.

(f) "Central axis of the beam" means a line passing through the virtual source and the center of the plane figure formed by the edge of the first beam-limiting device.

(g) "Cephalometric device" means a device intended for the radiographic visualization and measurement of the dimensions of the human head.

(h) "Certifiable cabinet X-ray system" means an existing, uncertified X-ray system that has been modified to meet the certification requirements specified in 21 C.F.R. 1020.40, ~~as in effect on April 30, 1984~~ dated April 1, 2019, which is hereby adopted by reference.

(i) "Certificate holder" means a person that has been issued a certificate of compliance or other package approval by the commission.

(j) "Certificate of compliance" and "CoC" mean the certificate issued by the commission under subpart D of 10 C.F.R. part 71, approving the design of a package for the transportation of radioactive material.

(k) "Certificate of registration" means a document issued by the department, the commission, or an agreement state given sealed source and device registry authority by the commission acknowledging the registration of a sealed source or device containing a sealed

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source.

(l) “Certified cabinet X-ray system” means a cabinet X-ray system that has been certified as manufactured and assembled as specified in 21 C.F.R. 1020.40, ~~as in effect on April 30, 1984~~ which is adopted by reference in subsection (h).

(j) (m) “Certified components” means the components of X-ray systems that are subject to regulations promulgated under public law 90-602, the radiation control for health and safety act of 1968 as amended.

(k) (n) “Certified system” means any X-ray system that has one or more certified components.

(h) (o) “Certifying entity” means an independent certifying organization or state regulatory program meeting the requirements in K.A.R. 28-35-293.

(m) (p) “Changeable filter” means any filter, exclusive of inherent filtration, that can be removed from the useful beam through any electronic, mechanical, or physical process.

(n) (q) “Chelating agent” means amine polycarboxylic acids, hydroxycarboxylic acids, gluconic acids, and polycarboxylic acids.

(o) (r) “Class” means a classification scheme for inhaled material according to its rate of clearance from the pulmonary region of the lung. For the purposes of these regulations, “lung class” and “inhalation class” shall be considered equivalent terms. Materials are classified as D, W, or Y, which applies to the following range of clearance half-times:

- (1) For class D, fewer than 10 days;
- (2) for class W, from 10 through 100 days; and

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(3) for class Y, more than 100 days.

(p) (s) “Coefficient of variation” and “C” mean the ratio of the standard deviation to the mean value of a population of observations. This ratio is estimated using the following equation:

$$C = \frac{s}{\bar{x}} = \frac{1}{\bar{x}} \left( \sum_{i=1}^n \frac{(x_i - \bar{x})^2}{n - 1} \right)^{1/2}$$

where

s = Estimated standard deviation of the population

$\bar{x}$  = Mean value of observations in sample

$x_i$  = ith observation in sample

(q) (t) “Collective dose” means the sum of the individual doses received in a given period of time by a specified population from exposure to a specified source of radiation.

(r) (u) “Collimator” means a radiation shield that is placed at the end of a guide tube or directly onto a radiographic exposure device to restrict the size of the radiation beam when the sealed source is cranked into position to make a radiographic exposure.

(s) (v) “Committed dose equivalent” and “ $H_{T,50}$ ” mean the dose equivalent to organs or tissues of reference (T) that will be received from an intake of radioactive material by an individual during the 50-year period following the intake.

(t) (w) “Committed effective dose equivalent” and “ $H_{E,50}$ ” mean the sum of the products of the weighting factors applicable to each of the body organs or tissues that are irradiated and the committed dose equivalent to each of these organs or tissues ( $H_{E,50} = \sum w_T H_{T,50}$ ).

(u) (x) “Computed tomography” means the production of a tomogram by the acquisition

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and computer processing of X-ray transmission data, including by cone beam-computed tomography.

~~(v)~~ (y) “Consortium” means an association of medical use licensees and a positron emission tomography (PET) radionuclide production facility in the same geographical area that jointly own or share the operation and maintenance cost of the PET radionuclide production facility that produces PET radionuclides for use in producing radioactive drugs within the consortium for noncommercial distributions among its associated members for medical use. The PET radionuclide production facility within the consortium shall be located at an educational institution, a federal facility, or a medical institution.

~~(w)~~ (z) “Contact therapy” means therapy in which the X-ray tube port is put in contact with, or within five centimeters of, the surface being treated.

~~(x)~~ (aa) “Contact therapy system” means a therapeutic radiation machine with a short target-to-skin distance (TSD), usually less than five centimeters.

(bb) “Contamination” means the presence of a radioactive substance on a surface in quantities of more than 0.4 Bq/cm<sup>2</sup> (1x10<sup>-5</sup> µCi/cm<sup>2</sup>) for beta and gamma emitters and low-toxicity alpha emitters, or 0.04 Bq/cm<sup>2</sup> (1x10<sup>-6</sup> µCi/cm<sup>2</sup>) for all other alpha emitters.

~~(y)~~ (cc) “Control cable” means the cable that is connected to the source assembly and used to drive the source to and from the exposure location.

~~(z)~~ (dd) “Control drive mechanism” means a device that enables the source assembly to be moved into and out of the exposure device.

~~(aa)~~ (ee) “Controlled area” means an area outside of a restricted area but inside the site

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boundary, access to which can be limited by the licensee or registrant for any reason.

~~(bb)~~ (ff) “Control panel” means that part of the X-ray system where the switches, knobs, push buttons, and other hardware necessary for manually setting the technique factors are mounted.

~~(ee)~~ (gg) “Control tube” means a protective sheath for guiding the control cable. The control tube connects the control drive mechanism to the radiographic exposure device.

~~(dd)~~ (hh) “Cooling curve” means the graphical relationship between the heat units stored and the cooling time.

(ii) “Criticality safety index” and “CSI” have the meaning specified for “criticality safety index (CSI)” in 10 C.F.R. 71.4, dated January 1, 2019. This definition is hereby adopted by reference.

~~(ee)~~ (jj) “Curie” means a unit of activity. One curie (Ci) is the quantity of radioactive material that decays at the rate of  $3.7 \times 10^{10}$  transformations per second (tps). Commonly used submultiples of the curie are the millicurie and the microcurie. One millicurie (mCi) = 0.001 curie =  $3.7 \times 10^7$  tps. One microcurie ( $\mu$ Ci) = 0.000001 curie =  $3.7 \times 10^4$  tps. (Authorized by K.S.A. 48-1607; implementing K.S.A. ~~2017~~ 2020 Supp. 48-1603 and K.S.A. 48-1607; effective Dec. 30, 2005; amended May 4, 2018; amended P-\_\_\_\_\_.)

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**28-35-135f. Definitions.** As used in these regulations, each of the following terms shall have the meaning ~~assigned~~ specified in this regulation:

(a) "Facility" means the specific location at which a person is licensed or registered to use radioactive material or radiation-producing devices. Separate physical locations shall be considered to be separate facilities.

(b) "Fail-safe characteristic" means a design feature that causes beam port shutters to close, or otherwise prevents emergence of the primary beam, upon the failure of a safety or warning device.

(c) "Field emission equipment" means equipment that uses an X-ray tube in which electron emission from the cathode is due solely to the action of an electric field.

(d) "Field-flattening filter" means a filter used to provide dose uniformity over the area of a useful beam of X-rays at a specified depth.

(e) "Field size" means the dimensions along the major axes of an area in a plane perpendicular to the specified direction of the beam of incident radiation at the normal treatment distance. Field size is defined by the intersection of the major axes and the 50 percent isodose line. Material shall be placed in the beam so that the maximum dose is produced at the normal treatment distance when the field size is being determined.

(f) "Field station" means a facility where radioactive sources or radiation-processing devices are stored or used and from which equipment is dispatched to temporary job sites.

(g) "Filter" means material placed in the path of the useful beam of X-rays to selectively absorb the less penetrating radiation.

(h) "Fixed contamination" means contamination that cannot be removed from a surface

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during normal conditions of transport.

(i) “Fluoroscopic imaging assembly” means a component that comprises a reception system in which X-ray photons produce a fluoroscopic image. This term shall include equipment housings, any electrical interlocks, the primary protective barrier, and structural material providing linkage between the image receptor and the diagnostic source assembly.

(j) “Focal spot” means the area projected on the anode of the X-ray tube by the electrons accelerated from the cathode and from which the useful beam originates.

(k) “Full-cost reimbursement” means reimbursement of the total cost of staff time and any contractual support services expended. (Authorized by K.S.A. 48-1607; implementing K.S.A. 2020 Supp. 48-1603 and K.S.A. 48-1607; effective Dec. 30, 2005; amended

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**28-35-135i. Definitions.** As used in these regulations, each of the following terms shall have the meaning specified in this regulation:

(a) "Image intensifier" means a device that instantaneously converts, by means of photoemissive surfaces and electronic circuitry, an X-ray pattern into a light pattern of greater intensity than would have been provided by the original X-ray pattern.

(b) "Image receptor" means any device, including a fluorescent screen and radiographic film, that transforms incident X-ray photons into a visible image or into another form that can be made into a visible image by further transformations.

(c) "Image receptor support," for mammographic systems, means that part of the system designed to support the image receptor in a horizontal plane during a mammographic examination.

(d) "Immediate" means within not more than 15 minutes or as otherwise defined in a license condition.

(e) "Incident" means an individual event or series of related events that caused or threatened to cause any violation of these regulations or license conditions. For the purposes of part 13, "incident" shall mean any unintended event involving radioactive material for which the public dose is a fraction of regulatory limits and safety provisions are sufficient, but further degradation of safety systems could lead to an accident.

(f) "Independent certifying organization" means an independent organization that meets all of the criteria specified in K.A.R. 28-35-293.

(g) "Indian tribe" and "tribe" mean ~~any Indian tribe, band, nation, or other organized group or community of Indians recognized as eligible for the services provided to Indians by the~~

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~~secretary of the United States department of the interior because of their status as Indians~~ an Indian or Alaska native tribe, band, nation, pueblo, village, or community that the secretary of the United States department of the interior acknowledges to exist as an Indian tribe pursuant to the federally recognized Indian tribe list act as specified by 25 U.S.C. 513, as amended.

(h) “Indian tribal official” and “tribal official” mean the highest-ranking individual who represents tribal leadership, including the chief, president, and tribal council leader.

(i) “Individual” means any human being.

(j) “Individual monitoring” means the assessment of either of the following:

(1) A dose equivalent by the use of individual-monitoring devices or by the use of survey data; or

(2) a committed effective dose equivalent determined by bioassay or by computation of the number of DAC-hours to which an individual is exposed.

(k) “Individual-monitoring device” means any device designed to be worn by a single individual for the assessment of dose equivalent. “Individual-monitoring device” shall include any film badge, thermoluminescent dosimeter (TLD), optically stimulated dosimeter, pocket ionization chamber, and personal air-sampling device. For purposes of these regulations, “~~personnel~~ personal dosimeter” and “dosimeter” shall be considered terms equivalent to “individual-monitoring device.”

(l) “Industrial radiography” means the examination of the structure of materials by nondestructive methods utilizing sources of radiation.

(m) “Inherent filtration” means the filtration permanently mounted in the useful beam,

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including the window of the X-ray tube and any permanent tube or source enclosure.

(n) "Injection tool" means a device used for controlled subsurface injection of radioactive tracer material.

(o) "Inspection" means an official examination or observation that may include tests, surveys, and monitoring to determine compliance with federal rules, state regulations, orders, requirements, and license and registration conditions.

(p) "Installation" means the location where one or more sources of radiation are used, operated, or stored.

(q) "Interlock" means a device for precluding access by an individual to an area of radiation hazard without warning, either by preventing admission or by automatically removing the hazards.

(r) "Internal dose" means that portion of the dose equivalent received from radioactive material taken into the body.

(s) "Interruption of irradiation" means the stopping of irradiation with the possibility of continuing irradiation without the resetting of operating conditions at the control panel.

(t) "Ionizing radiation" means radiation capable of producing an ionization event, including gamma rays and X-rays, alpha and beta particles, high-speed electrons, neutrons, and other nuclear particles.

(u) "Irradiation" means the exposure of matter to ionizing radiation.

(v) "Irradiator" means a facility that uses radioactive sealed sources for the irradiation of objects or materials and in which radiation dose rates exceeding five grays (500 rads) per hour

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exist at one meter from the sealed radioactive sources in air or water, as applicable for the irradiator type. This term shall not include any irradiator in which both the sealed source and the area subject to irradiation are contained within a device and are not accessible to personnel.

(w) "Irradiator operator" means an individual who has successfully completed the required training and testing and is authorized by the terms of the license to operate an irradiator without a supervisor present.

(x) "Irretrievable well-logging source" means any sealed source containing licensed material that is pulled off or not connected to the wireline that suspends the source in the well and for which all reasonable effort at recovery has been expended.

(y) "Isocenter" means a fixed point in space that is located at the center of the smallest sphere through which the central axis of the beams passes under all conditions. (Authorized by K.S.A. 48-1607; implementing K.S.A. ~~2017~~ 2020 Supp. 48-1603 and K.S.A. 48-1607; effective Dec. 30, 2005; amended May 4, 2018; amended P-\_\_\_\_\_.)

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**28-35-1351. Definitions.** As used in these regulations, each of the following terms shall have the meaning assigned specified in this regulation:

(a) "Lead equivalent" means the thickness of lead affording the same attenuation, under specified conditions, as the material in question.

(b) "Leakage radiation" means radiation emanating from the device source assembly, except for the following:

- (1) The useful beam; and
- (2) radiation produced when the exposure switch or timer is not activated for diagnosis or therapy.

(c) "Leakage technique factors" means the technique factors associated with the tube housing assembly that are used in measuring leakage radiation. The leakage technique factors shall be defined as follows:

(1) For diagnostic source assemblies intended for capacitor energy storage equipment, the maximum rated number of exposures in an hour for operation at the maximum rated peak tube potential, with the quantity of charge per exposure being 10 millicoulombs or the minimum obtainable from the unit, whichever is larger;

(2) for diagnostic source assemblies intended for field emission equipment rated for pulsed operation, the maximum rated number of X-ray pulses in an hour for operation at the maximum rated peak tube potential; and

(3) for all other diagnostic or therapeutic source assemblies, the maximum rated peak tube potential and the maximum rated continuous tube current for the maximum rated peak tube potential.

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(d) "License" means a document issued in accordance with these regulations specifying the conditions of use of radioactive material.

(e) "Licensed or registered material" means radioactive material received, possessed, used, transferred, or disposed of under a general or specific license or registration issued by the department.

(f) "Licensee" means any person ~~who~~ that is licensed in accordance with these regulations.

(g) "Licensing state" means any state that has been granted final designation by the conference of radiation control program directors, inc., for the regulatory control of NARM, as defined in K.A.R. 28-35-135n.

(h) "Light field" means that area of the intersection of the light beam from the beam-limiting device and one plane in the set of planes parallel to and including the plane of the image receptor, ~~whose~~ in which the perimeter is the locus of points at which the illumination is one-fourth of the maximum in the intersection.

(i) "Line-voltage regulation" means the difference between the no-load and the load line potentials, expressed as a percent of the load line potential, using the following equation:

$$\text{Percent line-voltage regulation} = 100 (V_n - V_l)/V_l$$

where

$V_n$  = No-load line potential and

$V_l$  = Load line potential

(j) "Local component" means any part of an analytical X-ray system. This term shall

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include components that are struck by X-rays, including radiation source housings, port and shutter assemblies, collimators, sample holders, cameras, goniometers, detectors, and shielding. This term shall not include power supplies, transformers, amplifiers, readout devices, and control panels.

(k) "Logging supervisor" means the individual who uses sources of radiation or provides personal supervision of the utilization of sources of radiation at a well site.

(l) "Logging tool" means a device used subsurface to perform well logging.

(m) "Lost or missing licensed or registered source of radiation" means a licensed or registered source of radiation whose location is unknown. This term shall include licensed or registered material that has been shipped but has not reached ~~its~~ the planned destination and whose location cannot be readily traced in the transportation system.

(n) "Lot tolerance percent defective" means the poorest quality, expressed as the percentage of defective units, in an individual inspection lot that may be accepted.

(o) "Low dose-rate remote afterloader" means a brachytherapy device that remotely delivers a dose rate of less than or equal to two grays per hour at the point or surface where the dose is prescribed.

(p) "Low specific activity material" and "LSA material" mean radioactive material with limited specific activity that is nonfissile material or is excepted under 10 C.F.R. 71.15 and that satisfies the descriptions and limits specified in these regulations. Shielding materials surrounding the LSA material shall not be considered in determining the estimated average specific activity of the package contents. The LSA material shall be classified in one of the

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following three groups:

(1) Group I, which shall consist of the following:

(A) Uranium and thorium ores, concentrates of uranium and thorium ores, and other ores containing naturally occurring radionuclides that are intended to be processed for the use of these radionuclides;

(B) natural uranium, depleted uranium, or natural thorium or the compounds or mixtures of natural uranium, depleted uranium, or natural thorium, if unirradiated and in solid or liquid form;

(C) radioactive material other than fissile material, for which the  $A_2$  value is unlimited;  
and

(D) other radioactive material in which the activity is distributed throughout, and the estimated average specific activity does not exceed 30 times the value for exempt material activity concentration determined in accordance with 10 C.F.R. part 71, appendix A, which is adopted by reference in K.A.R. 28-35-221b;

(2) group II, which shall consist of the following:

(A) Water with tritium concentration no more than 0.8 TBq/liter (20.0 Ci/liter); and

(B) other radioactive material in which the activity is distributed throughout and the estimated average specific activity does not exceed  $10^{-4} A_2/g$  for solids and gases and  $10^{-5} A_2/g$  for liquids; or

(3) group III solids, which shall include consolidated wastes and activated materials that meet the requirements of 10 C.F.R. 71.77 but shall exclude powders that meet the following

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conditions:

(A) The radioactive material is distributed throughout the solid or a collection of solid objects or is essentially uniformly distributed in a solid compact binding agent, including concrete, bitumen, and ceramic;

(B) the radioactive material is relatively insoluble or it is intrinsically contained in a relatively insoluble material so that even under loss of packaging, the loss of radioactive material per package by leaching when placed in water for seven days will not exceed 0.1 A<sub>2</sub>; and

(C) the estimated average specific activity of the solid, excluding any shielding material, does not exceed  $2 \times 10^{-3}$  A<sub>2</sub>/g. (Authorized by K.S.A. 48-1607; implementing K.S.A. 2020 Supp. 48-1603 and K.S.A. 48-1607; effective Dec. 30, 2005; amended March 18, 2011; amended P-\_\_\_\_\_.)

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**28-35-135m. Definitions.** As used in these regulations, each of the following terms shall have the meaning assigned specified in this regulation:

(a) “mA” means milliamperere.

(b) “Major processor” means a user processing, handling, or manufacturing radioactive material exceeding type A quantities as unsealed sources or material, or exceeding four times the type B quantities as sealed sources. This term shall not include nuclear medicine programs, universities, industrial radiographers, and small industrial programs. Type A and B quantities are specified in K.A.R. 28-35-221b ~~of these regulations~~.

(c) “Management” means the chief executive officer or other individual having the authority to manage, direct, or administer the licensee’s activities, or that person’s delegate or delegates.

(d) “Manual brachytherapy” means a type of brachytherapy in which the brachytherapy sources, including seeds and ribbons, are manually placed topically on or inserted either into the body cavities that are in close proximity to a treatment site or directly into the tissue volume.

(e) “mAs” means the product of milliamperes and seconds.

(f) “Master materials license” and “MML” mean a type of license issued by the nuclear regulatory commission that meets the following conditions:

(1) Authorizes the use of radioactive material at multiple sites;

(2) authorizes a licensee to issue permits for the possession and use of licensed or registered material; and

(3) provides for oversight and internal licensee inspection of the licensee’s permittees.

(g) “Maximum line current” means the root-mean-square current in the supply line of an

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X-ray machine operating at its maximum rating.

~~(g)~~ (h) “Medical event” means an event that meets the criteria specified in part 6 of these regulations.

~~(h)~~ (i) “Medical institution” means an organization in which several medical disciplines are practiced.

~~(i)~~ (j) “Medical use” means the intentional internal or external administration of radioactive material, or radiation, to humans in the practice of the healing arts.

~~(j)~~ (k) “Medium dose-rate remote afterloader” means a brachytherapy device that remotely delivers a dose rate of greater than two grays, but less than 12 grays per hour at the point or surface where the dose is prescribed.

~~(k)~~ (l) “Megavolt (MV)” ~~means~~ and “MV” mean the energy equal to that acquired by a particle with one electron charge in passing through a potential difference of one million volts in a vacuum.

~~(l)~~ (m) “Member of the public” means an individual, except when that individual is receiving an occupational dose.

~~(m)~~ (n) “Mineral logging” means logging performed for the purpose of mineral exploration other than oil or gas.

~~(n)~~ (o) “Minor” means an individual younger than 18 years of age.

~~(o)~~ (p) “Mobile nuclear medicine service” means the transportation and medical use of radioactive material.

~~(p)~~ (q) “Mobile X-ray equipment” means X-ray equipment mounted on a permanent base

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with wheels or casters, or both, for moving while completely assembled. This term shall include X-ray equipment mounted in a vehicle.

(q) (r) "Monitoring" means the measurement of radiation, radioactive material concentrations, surface area activities, or quantities of radioactive material and the use of the results of these measurements to evaluate potential exposures and doses. For purposes of these regulations, "radiation monitoring" and "radiation protection monitoring" shall be considered terms equivalent to "monitoring."

(r) (s) "Moving beam therapy" means radiation therapy with relative displacement of the useful beam and the patient during irradiation, including therapy, skip therapy, and rotational therapy. (Authorized by K.S.A. 48-1607; implementing K.S.A. 2020 Supp. 48-1603 and K.S.A. 48-1607; effective Dec. 30, 2005; amended P-\_\_\_\_\_.)

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**28-35-135n. Definitions.** As used in these regulations, each of the following terms shall have the meaning ~~assigned~~ specified in this regulation:

(a) "NARM" means any naturally occurring or accelerator-produced radioactive material, not including ~~byproduct~~ by-product, source, or special nuclear material.

(b) "Nationally tracked source" means a sealed source containing any quantity of radioactive material equal to or greater than any threshold listed in the table in this subsection. For purposes of the definition of "nationally tracked source," "sealed source" shall be defined as radioactive material that is sealed in a capsule or closely bonded, that is in a solid form, and that is not exempt from regulatory control. For purposes of the definition of "nationally tracked source," "sealed source" shall not include any radioactive material encapsulated solely for disposal and any nuclear material contained in any fuel assembly, subassembly, fuel rod, or fuel pellet. Category 1 nationally tracked sources contain radioactive material in quantities equal to or greater than the category 1 threshold. Category 2 nationally tracked sources contain radioactive material in quantities equal to or greater than the category 2 threshold but less than the category 1 threshold.

Radioactive material	Nationally tracked source thresholds			
	Category 1	Category 1	Category 2	Category 2
	(TBq)*	(Ci)**	(TBq)*	(Ci)**
Actinium-227	20	540	0.2	5.4
Americium-241	60	1,600	0.6	16
Americium-241/Be	60	1,600	0.6	16
Californium-252	20	540	0.2	5.4

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Cobalt-60	30	810	0.3	8.1
Curium-244	50	1,400	0.5	14
Cesium-137	100	2,700	1	27
Gadolinium-153	1,000	27,000	10	270
Iridium-192	80	2,200	0.8	22
Plutonium-238	60	1,600	0.6	16
Plutonium-239/Be	60	1,600	0.6	16
Polonium-210	60	1,600	0.6	16
Promethium-147	40,000	1,100,000	400	11,000
Radium-226	40	1,100	0.4	11
Selenium-75	200	5,400	2	154
Strontium-90	1,000	27,000	10	270
Thorium-228	20	540	0.2	5.4
Thorium-229	20	540	0.2	5.4
Thulium-170	20,000	540,000	200	5,400
Ytterbium-169	300	8,100	3	81

\* The Terabecquerel (TBq) values are the regulatory standard.

\*\* The curie (Ci) values specified are obtained by converting from the TBq value. The curie values are provided for practical usefulness and are rounded after conversion.

(c) "Natural radioactivity" means the radioactivity of naturally occurring nuclides.

(d) "New equipment" means any system subject to K.A.R. 28-35-249 that was

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~~manufactured after January 1, 1985~~ “Non-fixed contamination” means contamination that can be removed from a surface during normal conditions of transport.

(e) “Nonionizing radiation” means radiation not capable of producing ionization, including sound and radio waves and visible, infrared, or ultraviolet light.

(f) “Non-stochastic effect” means a health effect, the severity of which varies with the dose and for which a threshold is believed to exist. For purposes of these regulations, “deterministic effect” shall be considered an equivalent term.

(g) “Normal operating procedures” means operating procedures for conditions suitable for routine purposes with shielding and barriers in place, including routine alignment procedures. This term shall not include maintenance procedures and routine and emergency radiation safety considerations.

(h) “Normal treatment distance” means either of the following:

(1) For electron irradiation, the distance from the virtual source to the surface along the central axis of the useful beam, as specified by the manufacturer; or

(2) for X-ray irradiation, the distance from the virtual source to the isocenter along the central axis of the useful beam. For non-isocentric equipment, this distance shall be the distance specified by the manufacturer.

(i) ~~“Nuclear regulatory commission (NRC)” means,~~ “NRC,” and “commission” mean the U.S. nuclear regulatory commission or its duly authorized representatives.

(j) “NVLAP” means the national voluntary laboratory accreditation program.

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(Authorized by K.S.A. 48-1607; implementing K.S.A. 2020 Supp. 48-1603 and K.S.A. 48-1607;  
effective Dec. 30, 2005; amended July 27, 2007; amended P-\_\_\_\_\_.)

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**28-35-135o. Definitions.** As used in these regulations, each of the following terms shall have the meaning assigned specified in this regulation:

(a) "Occupational dose" means the dose received by an individual in the course of employment in which the individual's assigned duties involve exposure to radiation or radioactive material from licensed or unlicensed sources of radiation. The term "occupational dose" shall not include any dose received under any of the following circumstances:

- (1) As background radiation;
- (2) as a patient from medical practices;
- (3) from voluntary participation in medical research programs; or
- (4) as a member of the public.

(b) "Off-site response organization" means any non-licensee off-site organization that could be needed to respond to an emergency, including local fire, police, ambulance, and hospital emergency management services.

(c) "Open-beam configuration" means an X-ray system in which an individual could accidentally place some part of the individual's body in the primary beam path during normal operation.

(d) "Ophthalmic physicist" means an individual who meets the following requirements:

(1) The requirements specified in 10 C.F.R. 35.59 and 35.433(a)(2), which are adopted by reference in K.A.R. 28-35-264; and

(2) identification as an ophthalmic physicist after obtaining one of the following:

(A) A specific medical use license issued by the nuclear regulatory commission or an agreement state;

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(B) a permit issued by the nuclear regulatory commission or an agreement state broad scope medical use licensee;

(C) a medical use permit issued by a nuclear regulatory commission master material licensee; or

(D) a permit issued by a nuclear regulatory commission master material licensee or broad scope medical use permittee.

(e) "Output" means the exposure rate or dose rate, or a quantity related in a known manner to these rates from a teletherapy unit for a specified set of exposure conditions.

(Authorized by K.S.A. 48-1607; implementing K.S.A. 2020 Supp. 48-1603 and K.S.A. 48-1607; effective Dec. 30, 2005; amended P-\_\_\_\_\_.)

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**28-35-135s. Definitions.** As used in these regulations, each of the following terms shall have the meaning specified in this regulation:

(a) "Sanitary sewerage" means a system of public sewers to carry off waste water and refuse. This term shall exclude sewage treatment facilities, septic tanks, and leach fields owned or operated by the licensee or registrant.

(b) "Scattered radiation" means radiation that, during its passage through matter, is deviated in direction.

(c) "Sealed source" means any radioactive material that is permanently encased in a capsule designed to prevent the leakage or escape of the radioactive material.

(d) "Secondary dose-monitoring system" means a system that terminates irradiation if the primary system fails.

(e) "Secondary protective barrier" means a barrier sufficient to attenuate stray radiation to the required degree.

(f) "Secretary" means secretary of the department of health and environment.

(g) "Seismic area" means any area where the probability of a horizontal acceleration in rock of more than 0.3 times the acceleration of gravity in 250 years is greater than 10 percent, as designated by the U.S. geological survey.

(h) "Shallow dose equivalent" and "H<sub>s</sub>," which apply to the external exposure of the skin or an extremity, mean the dose equivalent at a tissue depth of 0.007 centimeter (7 mg/cm<sup>2</sup>) averaged over an area of one square centimeter.

(i) "Sheltering" means using a structure for radiation protection from an airborne plume containing radioactive material.

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(j) "Shielded position" means the location within the radiographic exposure device or storage container that, by the manufacturer's design, is the proper location for storage of the sealed source.

(k) "Shielded-room radiography using radiation machines" means industrial radiography using radiation machines that meets the following conditions:

(1) Is conducted in an enclosed room, the interior of which is not occupied during radiographic operations;

(2) is shielded so that every location on the exterior meets the conditions specified in K.A.R. 28-35-214a; and

(3) is accessible only through openings that are interlocked so that the radiation machine will not operate unless all openings are securely closed.

(l) "SI" means the abbreviation for the international system of units.

(m) "Shutter" means a device attached to an X-ray tube housing assembly that can totally intercept the useful beam and that has a lead equivalency not less than that of the tube housing assembly.

(n) "Sievert" means the SI unit of any of the quantities expressed as a dose equivalent. The dose equivalent in sieverts is equal to the absorbed dose in grays multiplied by the quality factor (1 Sv = 100 rem).

(o) "Site area emergency" means an event that could occur, is in progress, or has occurred, that could lead to a significant release of radioactive material, and that could require a response by off-site response organizations to protect persons off-site.

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(p) "Site boundary" means that line beyond which the land or property is not owned, leased, or otherwise controlled by the licensee or registrant.

(q) "Source" means the focal spot of the X-ray tube.

(r) "Source assembly" means an assembly that consists of the sealed source and a connector that attaches the source to the control cable.

(s) "Source changer" means a device designed and used for replacement of sealed sources in radiographic exposure devices, including those devices also used for transporting and ~~storing~~ storing sealed sources.

(t) "Source holder" means a housing or assembly into which a radioactive source is placed for the purpose of facilitating the handling and use of the source in well-logging operations.

(u) "Source-image receptor distance" and "SID" mean the distance from the source to the center of the input surface of the image receptor.

(v) "Source material" means the following:

(1) Uranium or thorium, or any combination of these, in any physical or chemical form;

or

(2) ores that contain, by weight, 0.05 percent or more of uranium, thorium, or any combination of these.

The term "source material" shall not include special nuclear material.

(w) "Source material milling" means any activity that results in the production of by-product material.

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(x) "Source of radiation" means any material, device, or equipment that emits or is capable of producing radiation.

(y) "Source-to-skin distance" and "SSD" mean the distance between the source and the patient's skin.

(z) "Special form" means any licensed material that meets either of the following conditions:

~~(1)(A) Is in solid form;~~

~~(B) has at least one dimension measuring at least five millimeters;~~

~~(C) does not melt, sublime, or ignite in air at a temperature of 1,000°F;~~

~~(D) does not shatter or crumble if subjected to the percussion test described in K.A.R. 28-35-144; and~~

~~(E) is not dissolved or converted into dispensable form to the extent of more than 0.005 percent by weight by immersion for one week in water at 68°F or in air at 86°F; or~~

~~(2)(A) Is in any physical form securely contained in a capsule;~~

~~(B) has at least one dimension measuring at least five millimeters;~~

~~(C) will retain its contents if subjected to the tests described in K.A.R. 28-35-144; and~~

~~(D) is constructed of materials that do not melt, sublime, or ignite in air at 1,475°F and do not dissolve or convert into dispensable form to the extent of more than 0.005 percent by weight by immersion for one week in water at 68°F or in air at 86°F. "Special form radioactive material" means radioactive material that meets the following conditions:~~

(1) The radioactive material is a single solid piece or is contained in a sealed capsule that

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can be opened only by destroying the capsule. The piece or capsule has at least one dimension not less than 5 mm (0.2 in).

(2) The piece or capsule meets the requirements of 10 C.F.R. 71.75, as in effect on August 19, 2020.

(3) The piece or capsule can be exempted from the requirements of 10 C.F.R. 71.75 and can continue to be used by meeting one of the following requirements:

(A) Was constructed before July 1, 1985 and designed in accordance with the requirements of 10 C.F.R. 71.4, as in effect on June 30, 1983;

(B) was constructed before April 1, 1998 and designed in accordance with the requirements of 10 C.F.R. 71.4, as in effect on March 31, 1996; or

(C) was successfully tested before September 10, 2015 in accordance with the requirements of 10 C.F.R. 71.75(d), as in effect before September 10, 2015.

(aa) "Special nuclear material" means either of the following:

(1) Plutonium, uranium-223, uranium enriched in the isotope 233 or in the isotope 235, and any other material that the department declares by order to be special nuclear material after the nuclear regulatory commission (NRC), pursuant to the provisions of section 51 of the atomic energy act of 1954, has determined the material to be special nuclear material, except for source material; or

(2) any material artificially enriched as specified in paragraph (aa)(1), except for source material.

(bb) "Special nuclear material in quantities not sufficient to form a critical mass" means

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any of the following:

(1) Uranium enriched in the isotope U-235, in quantities not exceeding 350 grams of contained U-235;

(2) uranium enriched in the isotope uranium-233, in quantities not exceeding 200 grams of contained U-233;

(3) plutonium not exceeding 200 grams; or

(4) any combination of these special nuclear materials in accordance with the following formula:

$$\frac{\text{grams of U-235}}{350} + \frac{\text{grams of U-233}}{200} + \frac{\text{gram of Pu}}{200} \leq 1$$

The sum of the ratios for all of the kinds of special nuclear material in combination shall not exceed one.

(cc) "Spot check" means a procedure that is performed to ensure that a previous calibration continues to be valid.

(dd) "Spot film" means a radiograph that is made during a fluoroscopic examination or radiation therapy treatment to permanently record conditions that exist during the procedure.

(ee) "Spot-film device" means a device intended either to transport and position a radiographic image receptor between the radiation source and image receptor or to position a radiographic image receptor between the radiation source and image receptor. This term shall

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include a device intended to hold a cassette over the input end of an image intensifier for the purpose of making a radiograph.

(ff) "Stationary beam therapy" means radiation therapy without relative displacement of the useful beam and the patient during irradiation.

(gg) "Stationary X-ray equipment" means X-ray equipment that is installed in a fixed location.

(hh) "Stereotactic radiosurgery" means the use of external radiation in conjunction with a stereotactic guidance device to very precisely deliver a therapeutic dose to a tissue volume.

(ii) "Stochastic effect" means a health effect that occurs randomly and for which the probability of the occurrence of the effect, rather than the severity of the effect, is assumed to be a linear function of dose without threshold. For purposes of these regulations, "probabilistic effect" shall be considered an equivalent term.

(jj) "Storage area" means any location, facility, or vehicle that is used to store, transport, or secure a radiographic exposure device, radiation machine, storage container, or sealed source when not in use. Each storage area shall be locked or have physical barriers to prevent accidental exposure, tampering, or unauthorized removal of the device, machine, sealed source, or container.

(kk) "Storage container" means a device in which radioactive materials are transported or stored.

(ll) "Stray radiation" means the sum of leakage radiation and scattered radiation.

(mm) "Structured educational program" means an educational program designed to

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impart particular knowledge and practical education through interrelated studies and supervised training.

(nn) "S-tube" means a tube through which the radioactive source travels when inside a radiographic exposure device.

(oo) "Subsurface studies" means the evaluation of parameters below the surface of the earth.

(pp) "Subsurface tracer study" means the release of a substance tagged with radioactive material for the purpose of tracing the movement or position of the tagged substance in the well bore or adjacent formation.

(qq) "Survey" means an evaluation of a radiation hazard resulting from the production, use, transfer, release, disposal, or presence of sources of radiation. This term shall include a physical survey of the location of materials or equipment, or both, and either the measurements of levels of radiation or the concentrations or quantities of radioactive materials present.

(Authorized by K.S.A. 48-1607; implementing K.S.A. 2017 2020 Supp. 48-1603 and K.S.A. 48-1607; effective Dec. 30, 2005; amended May 4, 2018; amended P-\_\_\_\_\_.)

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**28-35-135u. Definitions.** As used in these regulations, each of the following terms shall have the meaning specified in this regulation:

(a) "Underwater irradiator" means an irradiator in which the sources always remain shielded underwater and humans do not have access to the sealed sources or the space that is subject to irradiation without entering the pool.

(b) "Underwater radiography" means industrial radiography performed when the radiographic exposure device or the related equipment is beneath the surface of the water.

(c) "Unit dose" means a dosage prepared for medical use for administration to a patient or human research subject as a single dosage, without any further manipulation of the dosage after the dosage is initially prepared.

(d) "Unrefined and unprocessed ore" means ore in its natural form before any processing, including grinding, roasting, beneficiating, and refining. "Processing" shall not include sieving or the encapsulation of ore or preparation of samples for laboratory analysis.

(e) "Unrestricted area" means an area to which access is neither limited nor controlled by the licensee or registrant. For purposes of these regulations, "uncontrolled area" shall be considered an equivalent term.

(f) "Uranium" means natural uranium, depleted uranium, or enriched uranium.

(1) "Natural uranium" shall mean uranium, which may be chemically separated, with the naturally occurring distribution of uranium isotopes approximately 0.711 percent by weight uranium-235 and the remainder by weight essentially uranium-238.

(2) "Depleted uranium" shall mean uranium containing less uranium-235 than the naturally occurring distribution of uranium isotopes.

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(3) “Enriched uranium” shall mean uranium containing more uranium-235 than the naturally occurring distribution of uranium isotopes.

(g) “Useful beam” means the part of the radiation that passes through a window, aperture, cone, or other collimating device. (Authorized by K.S.A. 48-1607; implementing K.S.A. 2017 2020 Supp. 48-1603 and K.S.A. 48-1607; effective Dec. 30, 2005; amended May 4, 2018; amended P-\_\_\_\_\_.)

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**28-35-178a. General license; certain ionization devices.** (a) Each commercial and industrial firm, research, educational, and medical institution, individual in the conduct of the individual's business, and federal, state, or local government agency shall be deemed to have been issued a general license to acquire, receive, possess, use, or transfer radioactive material incorporated in any device or equipment as described in this subsection, if the device or equipment is manufactured, tested, and labeled by a manufacturer in accordance with the specifications of a specific license issued to the manufacturer by the secretary, the U.S. nuclear regulatory commission, or an agreement state. This general license shall apply to the following:

(1) Static elimination devices ~~that are designed for ionization of air and~~ that contain, as a sealed source or sources, ~~radioactive material containing~~ by-product material consisting of a total of not more than 18.5 MBq (500 microcuries) of polonium-210 per device; ~~and~~

(2) ion-generating tubes that are designed for ionization of air and that contain, as a sealed source or sources, radioactive material consisting of a total of not more than 500 microcuries of polonium-210 per device or a total of not more than 50 millicuries of hydrogen-3 (tritium) per device; and

(3) devices or equipment authorized before October 23, 2012 for use under the general license provided in 10 C.F.R. 31.3 and equivalent regulations of agreement states and the nuclear regulatory commission and manufactured, tested, and labeled by the manufacturer in accordance with the specifications contained in a specific license issued by the department.

(b) The general license specified in subsection (a) shall be subject to the following regulations:

(1) K.A.R. 28-35-137 through 28-35-139;

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(2) K.A.R. 28-35-192b;

(3) K.A.R. 28-35-184a;

(4) K.A.R. 28-35-190a;

(5) K.A.R. 28-35-191a;

(6) K.A.R. 28-35-196a; and

(7) all of parts 4 and 10 of these regulations. (Authorized by and implementing K.S.A. 48-1607; effective, T-86-37, Dec. 11, 1985; effective May 1, 1986; amended Dec. 30, 2005; amended July 27, 2007; amended P-\_\_\_\_\_.)

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**28-35-178i. General licenses for certain units of radium-226.** (a) Subject to the limitations in subsections (b), (c), and (d), a general license is hereby issued to any person to acquire, possess, use, and transfer radium-226 contained in the following products if manufactured before the effective date of this regulation:

(1) Antiquities originally intended for use by the general public. For the purposes of this paragraph, “antiquities” shall mean products originally intended for use by the general public and distributed in the late 19th and early 20th centuries, including radium emanator jars, revigators, radium water jars, radon generators, refrigerator cards, radium bath salts, and healing pads;

(2) intact timepieces containing more than 0.037 megabecquerel (1 microcurie), nonintact timepieces, and timepiece hands and dials no longer installed in timepieces;

(3) luminous items installed in air, marine, or land vehicles;

(4) all other luminous products not listed in this subsection, if not more than 100 items are used or stored at the same location at any one time; and

(5) small radium sources containing not more than 0.037 megabecquerel (1 microcurie) of radium-226. For the purposes of this paragraph, “small radium sources” shall mean discrete survey instrument check sources; sources contained in radiation-measuring instruments; sources used in educational demonstrations, including cloud chambers and spinthariscopes; electron tubes; lightning rods; ionization sources; static eliminators; and small radium sources designated by the commission.

(b) A person shall not acquire, possess, use, or transfer radium-226 pursuant to the general license issued in subsection (a) until the person has filed form RH-37 with the secretary and has received from the secretary a validated copy of the form, with a certification number

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assigned. Each person filing a form RH-37 shall provide all the information required by that form.

(c) Each person ~~who~~ that acquires, receives, possesses, uses, or transfers by-product material in accordance with the general license issued in subsection (a) shall meet the following requirements:

(1) Notify the department of any indication of possible damage to the product that indicates a potential loss of the radioactive material. A report containing a brief description of the event and the remedial action taken shall be provided to the department within 30 days of the incident;

(2) not abandon any products containing radium-226. The product and any radioactive material from the product shall be disposed of only according to K.A.R. 28-35-165 or by transfer to a person authorized by a specific license to receive the radium-226 in the product or as otherwise approved by the department;

(3) not export any products containing radium-226 except in accordance with K.A.R. 28-35-178b;

(4) dispose of any products containing radium-226 at a disposal facility authorized to dispose of radioactive material in accordance with any federal or state solid or hazardous waste law, including the solid waste disposal act of 1965, 42 U.S.C. 6901 through 6992k as amended, as authorized under 42 U.S.C. 15801 et seq., by transfer to a person authorized to receive radium-226 by a specific license issued under K.A.R. 28-35-180a or equivalent regulations of an agreement state or the commission, or as otherwise approved by the department; and

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(5) respond to any written request from the department to provide information relating to the general license within 30 calendar days of the date of the request or other time specified in the request. If the general licensee cannot provide the requested information within the allotted time, that licensee shall, within that same time period, request a longer period to supply the information by submitting a letter to the department and shall provide written justification as to why the person cannot comply.

(d) Each general licensee under this regulation shall file with the secretary a written report of any changes in the information filed in form RH-37. The report shall be furnished within 30 days after the effective date of the change.

(e) ~~Each general licensee under this regulation shall be exempt from the requirements of parts 4 and 10 of these regulations with respect to the radioactive material covered by the general license.~~ Each person that acquires, receives, possesses, uses, or transfers by-product material under the general license issued under this regulation shall be exempt from the provisions of parts 4 and 10 of these regulations to the extent that the receipt, possession, use, or transfer of by-product material is within the terms of the general license. This exemption shall not apply to any person issued a specific license under these regulations.

(f) The general license specified in subsection (a) shall not authorize the manufacture, assembly, disassembly, repair, or import of any products containing radium-226, except that timepieces may be disassembled and repaired.

(g) Any general licensee under this regulation who is an individual member of the public may submit an application to the department for a waiver from the general license fee prescribed

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K.A.R. 28-35-178i, page 4

in K.A.R. 28-35-147a. (Authorized by and implementing K.S.A. 48-1607; effective, T-86-37,  
Dec. 11, 1985; effective May 1, 1986; amended May 4, 2018; amended P-\_\_\_\_\_.)

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**28-35-181d. Specific licenses for one or more groups of medical uses.** (a) Any institution, person, or group of persons meeting the requirements of K.A.R. 28-35-181a or 28-35-181b may file a written application with the secretary for a specific license to use radioactive material for any group or groups of medical uses. Each application shall meet the requirements of K.A.R. 28-35-179a and shall designate the intended group or groups of uses for the radioactive material.

(b) Each application for a specific license to use radioactive material for any group or groups of medical uses shall meet all of the following requirements:

(1) The applicant, or the physician or physicians designated in the application as the individual user or users, has adequate clinical experience in performing the medical use or uses for which application is made.

(2) The applicant's proposed radiation detection instrumentation is adequate for conducting the medical procedures specified in the group or groups of uses for which application is made.

(3) The applicant's radiation safety operating procedures are adequate for the proper handling and disposal of radioactive material involved in the group or groups of uses for which application is made.

(4) The applicant, or the physician or physicians designated in the application as the individual user or users, and all other personnel who will be involved in the preparation and use of the radioactive material have adequate training and experience in the handling of radioactive material. The training and experience shall be appropriate for the conduct of the uses included in the group or groups of uses for which application is made.

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(c) Each licensee who is licensed under this regulation shall be subject to the following limitations:

(1) A licensee who has been issued a license for group I, II, IV, or V uses shall not receive, possess, or use radioactive material, except those radiopharmaceuticals manufactured in the form to be administered to the patient, and labeled, packaged, and distributed in accordance with a specific license issued by the secretary, or the ~~United States~~ nuclear regulatory commission or an agreement state.

(2) A licensee who has been issued a license for group III uses shall not receive, possess, or use generators or reagent kits containing radioactive material and shall not use reagent kits that do not contain radioactive material to prepare radiopharmaceuticals containing radioactive material, except for the following:

(A) Reagent kits not containing radioactive material that are approved by the secretary, the ~~United States~~ nuclear regulatory commission, or an agreement state for use by persons licensed pursuant to this regulation for group III medical uses; or

(B) generators or reagent kits containing radioactive material that are manufactured, labeled, packaged, and distributed in accordance with a specific license issued by the secretary, the ~~United States~~ nuclear regulatory commission, or an agreement state.

(3) Each licensee who has been issued a license for group III uses and who uses generators or reagent kits shall elute the generator or process radioactive material with the reagent kit in accordance with instructions that are approved by the secretary, the ~~United States~~ nuclear regulatory commission, or an agreement state and furnished by the manufacturer on the

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label attached to, or in the leaflet or brochure that accompanies, the generator or reagent kit.

(4) Each licensee preparing technetium-99m radiopharmaceuticals from molybdenum-99 or technetium-99m generators or rubidium-82 from strontium-82 or rubidium-82 generators shall test the generator eluates for molybdenum-99 breakthrough or for strontium-82 and strontium-85 contamination, respectively, in accordance with part 3 of these regulations. Each licensee shall record the results of each test and shall retain each record for three years after the record is made. Each licensee shall report to the department the results of each test that exceeds the permissible concentration in accordance with part 3 of these regulations at the time of generator elution.

(5) Each licensee who has been issued a license for ~~groups~~ group I, II, or III uses and who uses the radioactive material for clinical procedures other than those specified in the product labeling or package insert shall comply with the product labeling regarding the following:

- (A) Chemical and physical form;
- (B) route of administration; and
- (C) dosage range.

~~(5)~~ (6) A licensee who has been issued a license for group IV uses shall not receive, possess, or use radioactive material unless contained in a source or device that has been manufactured, labeled, packaged, and distributed in accordance with a specific license issued by the secretary, the ~~United States~~ nuclear regulatory commission, or an agreement state.

(d) Each licensee who is licensed under this regulation shall be authorized to use radioactive material under the general license issued in K.A.R. 28-35-178h for the specified in vitro uses, without filing form RH-31 as otherwise required by that regulation. However, the

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licensee shall be subject to the other requirements of K.A.R. 28-35-178h.

(e) Each licensee who is licensed under this regulation shall be authorized, subject to the provisions of subsections (f) and (g), to receive, possess, and use the following for calibration and reference standards:

(1) Any radioactive material listed in ~~groups~~ group I, II, or III that has a half-life of 100 days or less, in amounts not exceeding 15 millicuries;

(2) any radioactive material listed in group I, II, or III that has a half-life ~~greater~~ of more than 100 days, in amounts not exceeding 200 microcuries;

(3) technetium-99m, in amounts not exceeding 30 millicuries; and

(4) any radioactive material, in amounts not exceeding three millicuries per source, contained in calibration or reference sources that have been manufactured, labeled, packaged, and distributed in accordance with a specific license issued by the secretary, the ~~United States~~ nuclear regulatory commission, or an agreement state.

(f)(1) Each licensee who possesses sealed sources as calibration or reference sources pursuant to subsection (e) shall cause each sealed source containing radioactive material, other than hydrogen 3, that has a half-life ~~greater~~ of more than 30 days and that is in any form other than gas to be tested for leakage, contamination, or both at intervals not exceeding six months. In the absence of a certificate from a transferor indicating that a leak test has been made within six months before the transfer of a particular sealed source, that sealed source shall not be used until tested, unless one of the following conditions is met:

(A) The source contains 100 microcuries or less of beta-emitting, gamma-emitting, or

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beta-emitting and gamma-emitting material, or 10 microcuries or less of alpha-emitting material.

(B) The sealed source is stored and is not being used.

(2) Each leak test required ~~under~~ by paragraph (f)(1) shall be capable of detecting the presence of 0.005 microcurie of radioactive material on the test sample. The test sample shall be taken from sealed source or from the surfaces of the device in which the sealed source is permanently mounted or stored and on which contamination might be expected to accumulate. Records of leak test results shall be kept in units of microcuries and shall be maintained for inspection by the department.

(3) If the leak test reveals the presence of 0.005 microcurie or more of removable contamination, the licensee shall immediately withdraw the sealed source from use and shall cause it to be decontaminated and repaired, or to be disposed of in accordance with parts 3 and 4 of these regulations. A report shall be filed with the secretary within five days of the test, describing the equipment involved, the test results, and the corrective action taken.

(g) Each licensee who possesses and uses calibration and reference sources pursuant to subsection (e) shall perform the following:

(1) Follow radiation safety and handling instructions that are approved by the secretary, the ~~United States~~ nuclear regulatory commission, or an agreement state and furnished by the manufacturer on the label attached to the source, or permanent container ~~thereof~~, or in the leaflet or brochure that accompanies the source;

(2) maintain the instructions referenced in paragraph (g)(1) in a legible and conveniently available form; and

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(3) conduct a quarterly physical inventory to account for all sources received and possessed. ~~Records of the inventories~~ A record of each inventory shall be maintained for inspection by the department and shall include the quantities and kinds of radioactive material, location of sources, and the date of the inventory. (Authorized by and implementing K.S.A. 48-1607; effective, T-86-37, Dec. 11, 1985; effective May 1, 1986; amended July 27, 2007; amended P-\_\_\_\_\_.)

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**28-35-181j. Specific licenses to manufacture and distribute calibration sources**

**containing americium-241 or radium-226.** (a) An application for a specific license to manufacture or initially transfer calibration or reference sources containing americium-241 or radium-226 for distribution to persons generally licensed under K.A.R. 28-35-178e shall not be approved unless the following requirements are met:

(1) The applicant shall satisfy the general requirements of part 3 of these regulations.

(2) The applicant shall submit sufficient information regarding each type of calibration or reference source pertinent to evaluation of the potential radiation exposure, including the following:

(A) Chemical and physical form and maximum quantity of americium-241 or radium-226 in the source;

(B) details of construction and design;

(C) details of the method of incorporation and binding of the americium-241 or radium-226 in the source;

(D) procedures for and results of prototype testing of sources that are designed to contain more than 0.005 microcurie of americium-241 or radium-226, to demonstrate that the americium-241 or radium-226 contained in each source will not be released or be removed from the source under normal conditions of use;

(E) details of quality control procedures to be followed in manufacture of the source;

(F) description of labeling to be affixed to the source or the storage container for the source; and

(G) any additional information, including experimental studies and tests, required by the

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department to facilitate a determination of the safety of the source.

(3) Each source shall contain no more than 5  $\mu\text{Ci}$  microcuries of americium-241 or radium-226. With respect to any type of source containing more than 0.005 microcurie of americium-241 or radium-226, it shall be determined by the secretary that

(4) the method of incorporation and binding of more than 0.005  $\mu\text{Ci}$  microcuries of the americium-241 or radium-226 in the source shall ~~prevent~~ prevents the release or removal of americium-241 or radium-226 from the source under normal conditions of use and handling of the source.

~~(5) (4) The applicant shall conduct prototype tests, in the order listed, on each of five prototypes of the source containing more than 0.185 kilobecquerel (0.005 microcurie) of americium-241 or radium-226, and the five prototype sources shall have passed the prototype test, as follows: The applicant shall subject at least five prototypes of each source that is designed to contain more than 0.185 kilobecquerel (0.005 microcurie) of americium-241 or radium-226 to the following tests:~~

(A) Initial measurement. The quantity of radioactive material deposited on the source shall be measured by direct counting of the source.

(B) Dry wipe Weathering test. ~~The entire radioactive surface of the source shall be wiped with filter paper with the application of moderate finger pressure. Removal of radioactive material from the source shall be determined by measuring the radioactivity on the filter paper or by direct measurement of the radioactivity on the source following the dry wipe. Each source shall be subjected to tests that adequately take into account the individual, aggregate, and~~

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cumulative effects of environmental conditions, including physical handling, moisture, and water immersion, expected in service that could adversely affect the effective containment or binding of americium-241 or radium-226. Each source shall be inspected for evidence of physical damage and for loss of americium-241 or radium-226 after each stage of testing, using methods of inspection adequate for determining compliance with the criteria specified in subsection (b).

(C) Wet wipe test. The entire radioactive surface of the source shall be wiped with filter paper, moistened with water, with the application of moderate finger pressure. Removal of radioactive material from the source shall be determined by measuring the radioactivity on the filter paper after the paper has dried or by direct measurement of the radioactivity on the source following the wet wipe.

(D) Water soak test. The source shall be immersed in water at room temperature for 24 consecutive hours. The source shall then be removed from the water. Removal of radioactive material from the source shall be determined by direct measurement of the radioactivity on the source after the source has dried or by measuring the radioactivity in the residue obtained by evaporation of the water in which the source was immersed.

(E) Dry wipe test. ~~On completion of the water soak test, the dry wipe test described in paragraph (a)(5)(B) shall be repeated.~~ A dry wipe test shall be performed on each source containing more than 3.7 kilobecquerels (0.1 microcurie) of americium-241 or radium-226 before transferring the source to a general licensee under K.A.R. 28-35-178e or under equivalent regulations of an agreement state. The dry wipe test shall be performed by wiping the entire radioactive surface of the source with a filter paper with the application of moderate finger

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pressure. The radioactivity on the filter paper shall be measured using a method capable of detecting 0.185 kilobecquerel (0.005 microcurie) of americium-241 or radium-226. If a source has been shown to be leaking or losing more than 0.185 kilobecquerel (0.005 microcurie) of americium-241 or radium-226 by any of the methods described in this subsection, the source shall be rejected and shall not be transferred to a general licensee under K.A.R. 28-35-178e or equivalent regulations of an agreement state.

(F) Observations. Removal of more than 0.005 microcurie of radioactivity in any test prescribed by paragraph (a)(5)(4) shall be cause for rejection of the source design. Results of prototype tests submitted to the nuclear regulatory commission shall be given in terms of radioactivity in microcuries and percent of removal from the total amount of radioactive material deposited on the source.

(6) Each source or storage container for the source shall have a label affixed that contains sufficient information about safe use and storage of the source and includes the following or an equivalent statement:

“The receipt, possession, use and transfer of this source, Model \_\_\_\_\_, Serial No. \_\_\_\_\_, are subject to a general license and the regulations of the United States Nuclear Regulatory Commission or of a State with which the commission has entered into an agreement for the exercise of regulatory authority. Do not remove this label.

CAUTION—RADIOACTIVE MATERIAL—THIS SOURCE CONTAINS AMERICIUM-241  
(or RADIUM-226). DO NOT TOUCH RADIOACTIVE PORTION OF THIS SOURCE.

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(Name of manufacturer or initial transferor).”

(b) Each person licensed under this regulation shall perform a dry wipe test upon each source containing more than 3.7 kilobecquerels (0.1 microcurie) of americium-241 or radium-226 before transferring the source to a general licensee in accordance with K.A.R. 28-35-178e or equivalent regulations of an agreement state or the nuclear regulatory commission. This test shall be performed by wiping the entire radioactive surface of the source with a filter paper with the application of moderate finger pressure.

The radioactivity on the paper shall be measured by using radiation detection instrumentation capable of detecting 0.185 kilobecquerel (0.005 microcurie) of americium-241 or radium-226. If this test discloses more than 0.185 kilobecquerel (0.005 microcurie) of radioactive material or if there is evidence of any physical damage, the source shall be deemed to be leaking or losing americium-241 or radium-226 and shall not be transferred to a general licensee in accordance with K.A.R. 28-35-178e or equivalent regulations of an agreement state or the nuclear regulatory commission. (Authorized by and implementing K.S.A. 48-1607; effective, T-86-37, Dec. 11, 1985; effective May 1, 1986; amended March 18, 2011; amended P-\_\_\_\_\_.)

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**28-35-181m. Specific licenses to manufacture, prepare, or distribute radiopharmaceuticals containing radioactive material for medical use.** An application for a specific license to manufacture, prepare, or distribute radiopharmaceuticals containing radioactive material and used by persons as specified in part 6 of these regulations shall not be approved unless the applicant meets the requirements of this regulation and all other applicable requirements of these regulations.

(a) Each applicant shall meet the requirements in K.A.R. 28-35-180a.

(b) Each applicant shall submit evidence of either of the following:

(1) The radiopharmaceutical containing radioactive material is subject to the federal food, drug and cosmetic act or the public health service act and will be manufactured, labeled, and packaged in accordance with a new drug application (NDA) approved by the U.S. food and drug administration (FDA), a biologic product license issued by the FDA, or a “notice of claimed investigational exemption for a new drug” (IND) accepted by the FDA.

(2) The manufacture and distribution of the radiopharmaceutical containing radioactive material is not subject to the federal food, drug, and cosmetic act or the public health service act.

(c) Each applicant shall submit evidence of at least one of the following:

(1) The applicant is registered or licensed with the ~~U.S. food and drug administration~~ FDA as a drug manufacturer.

(2) The applicant is registered or licensed with a state agency as a drug manufacturer.

(3) The applicant is licensed as a pharmacy by the state board of pharmacy.

(4) The applicant is operating as a nuclear pharmacy within a federal medical institution.

(5) The applicant is operating a positron emission tomography (PET) drug production

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facility.

(d) Each applicant shall submit the following information on the radionuclide:

(1) The chemical and physical form of the material;

(2) the packaging in which the radionuclide is shipped, including the maximum activity per package; and

(3) evidence that the shielding provided by the packaging of the radioactive material is appropriate for the safe handling and storage of radiopharmaceuticals by group licensees.

(e)(1) Each applicant shall ~~submit a description of the following~~ comply with the following labeling requirements:

(A) A label that shall be affixed to each transport radiation shield, whether the shield is constructed of lead, glass, plastic, or other material, of a radioactive drug to be transferred for commercial distribution. The label shall include the following:

(i) The radiation symbol and the words “CAUTION – RADIOACTIVE MATERIAL” or “DANGER – RADIOACTIVE MATERIAL”;

(ii) the name of the radioactive drug and the abbreviation; and

(iii) the quantity of radioactivity at a specified date and time. For radioactive drugs with a half-life greater than 100 days, the time may be omitted; and

(B) a label that shall be affixed to each syringe, vial, or other container used to hold a radioactive drug to be transferred for commercial distribution. The label shall include the radiation symbol and the words “CAUTION – RADIOACTIVE MATERIAL” or “DANGER – RADIOACTIVE MATERIAL” and an identifier that ensures that the syringe, vial, or other

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container can be correlated with the information on the transport radiation shield label.

(2) The labels, leaflets, or brochures required by this regulation shall be made in addition to the labeling required by the FDA. The labels, leaflets, or brochures may be separate from the FDA labeling, or with the approval of the FDA, the labeling may be combined with the labeling required by the FDA.

(f) All of the following shall apply to each licensee described in paragraph (c)(3) or (c)(4), or both:

(1) The licensee may prepare radioactive drugs for medical use, if each radioactive drug is prepared by either an authorized nuclear pharmacist, as specified in paragraphs (2) and (4) of this subsection, or an individual under the supervision of an authorized nuclear pharmacist.

(2) The licensee may allow a pharmacist to work as an authorized nuclear pharmacist if at least one of the following conditions is met:

(A) The pharmacist meets the requirements in 10 C.F.R. 35.55(b) and 35.59 as adopted by reference in K.A.R. 28-35-264, and the licensee has received an approved license amendment identifying this individual as an authorized nuclear pharmacist.

(B) The pharmacist is designated as an authorized nuclear pharmacist in accordance with paragraph (4) of this subsection.

(C) The pharmacist qualifies as an authorized nuclear pharmacist as defined in 10 C.F.R. 35.2, as adopted by reference in K.A.R. 28-35-264.

(3) The actions authorized in paragraphs (1) and (2) of this subsection shall be permitted in spite of more restrictive language in license conditions.

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(4) The licensee may designate a pharmacist as an authorized nuclear pharmacist if at least one of the following conditions is met:

(A) The individual was a nuclear pharmacist preparing only radioactive drugs containing accelerator-produced radioactive material.

(B) The individual practiced at a government agency or federally recognized Indian tribe pharmacy before November 30, 2007 or at any other pharmacy before August 8, 2009.

(5) Each licensee shall provide a copy of the state pharmacy license or registration, not later than 30 days after the date that the licensee allows for an individual to work as an authorized nuclear pharmacist under paragraph (2) of this subsection, and one of the following documents to the department:

(A) The individual's certification by a specialty board whose certification process has been recognized as specified in 10 C.F.R. 35.55(a), as adopted by reference in K.A.R. 28-35-264;

(B) a department, NRC, or agreement state license listing the individual as an authorized nuclear pharmacist;

(C) an NRC master materials licensee permit listing the individual as an authorized nuclear pharmacist;

(D) a permit issued by a licensee of broad scope or an NRC master materials permittee or the authorization from a commercial nuclear pharmacy that is authorized to list its own authorized nuclear pharmacist; or

(E) documentation that only accelerator-produced radioactive materials were used in

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the practice of nuclear pharmacy at a government agency or federally recognized Indian tribe before November 30, 2007 or at all other locations of use before August 8, 2009, or an earlier date noticed by the NRC as permitted by 10 C.F.R. 35.13(b)(5).

~~(g) Each licensee shall possess and use instrumentation to measure the radioactivity of radioactive drugs. Each licensee shall have procedures for using the instrumentation. Each licensee shall measure, by direct measurement or by combination of measurements and calculations, the amount of radioactivity in dosages of alpha, beta, or photon emitting radioactive drugs before transfer for commercial distribution. Each licensee shall meet the following requirements:~~

~~(1) Perform tests before initial use, periodically, and following repair on each instrument for accuracy, linearity, and geometry dependence, as appropriate for the use of the instrument, and make adjustments if necessary; and~~

~~(2) check each instrument for constancy and proper operation at the beginning of each day of use.~~

~~(h) Each application from a medical facility, an educational institution, or a federal facility to produce positron emission tomography (PET) radioactive drugs for noncommercial transfer to licensees within the applicant's consortium authorized for medical use under part 6 of these regulations or equivalent agreement state requirements shall include the following:~~

~~(1) A request for authorization for the production of PET radionuclides or evidence of an existing license issued under these regulations or equivalent NRC or agreement state requirements for a PET radionuclide production facility within the applicant's consortium from~~

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which the applicant receives PET radionuclides;

(2) evidence that the applicant is qualified to produce radioactive drugs for medical use by meeting the requirements of this regulation subsection (c);

(3) the name of each individual authorized to prepare PET radioactive drugs if the applicant is a pharmacy and documentation that each individual meets the requirements of an authorized nuclear pharmacist as specified in paragraphs (f)(2) and (f)(4); and

(4) the name of each PET radioactive drug for production and noncommercial distribution to the applicant's consortium, including the chemical and physical form of each drug.

(h) Each licensee licensed under subsection (g) for the production of positron emission tomography (PET) radioactive drugs for noncommercial transfer to licensees within the applicant's consortium authorized for medical use under part 6 of these regulations or equivalent agreement state requirements shall meet the following requirements:

(1) Comply with the labeling requirements specified in subsection (e);

(2) possess and use instrumentation to measure the radioactivity of PET radioactive drugs intended for noncommercial distribution to members of the licensee's consortium and have procedures for using the instrumentation;

(3) measure, by direct measurement or by a combination of measurements and calculations, the amount of radioactivity in dosages of alpha-, beta-, or photon-emitting radioactive drugs before transfer for commercial distribution;

(4) perform tests before initial use, periodically, and following repair on each instrument for accuracy, linearity, and geometry dependence, as appropriate for the use of the instrument,

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and make adjustments if necessary; and

(5) check each instrument for constancy and proper operation at the beginning of each day of use.

(i) Nothing in these regulations shall exempt the licensee from the requirement to comply with applicable FDA requirements and other federal and state requirements governing radioactive drugs. (Authorized by and implementing K.S.A. 48-1607; effective, T-86-37, Dec. 11, 1985; effective May 1, 1986; amended Dec. 30, 2005; amended July 27, 2007; amended March 18, 2011; amended May 4, 2018; amended P-\_\_\_\_\_.)

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**28-35-181r. Special licenses to manufacture, process, import, distribute, or transfer certain radioactive material to persons exempt from regulation pursuant to K.A.R. 28-35-**

**192a.** (a) An application for a specific license to manufacture, process, produce, import, package, repack, or transfer quantities of radioactive material other than source, ~~by-product~~ by-product, or special nuclear material for commercial distribution to persons exempt from these regulations pursuant to K.A.R. 28-35-192a or an equivalent regulation of the ~~United States~~ nuclear regulatory commission or an agreement state shall not be approved unless the applicant submits the information required in ~~10 CFR sections~~ C.F.R. 32.18 and 32.19, as in effect on March 31, 1983 dated January 1, 2019, which are hereby adopted by reference.

(b) Each device shall be registered in the sealed source and device registry as defined in 10 C.F.R. 32.2 and maintained by the NRC.

(c) Each person licensed under subsection (a) ~~of this regulation~~ shall maintain records identifying, by name and address, each person to whom the licensee transfers radioactive material and stating the kinds and quantities of radioactive material transferred. An annual summary report stating the total quantity of each isotope transferred shall be filed with the department. Each report shall cover the 12-month period ~~commencing~~ beginning on July 1 and ending June 30 and shall be filed ~~by~~ on or before July 31 of each year. If no transfers of radioactive material have been made during a reporting period, the report shall indicate this fact. (Authorized by and implementing K.S.A. 1984 Supp. 48-1607; effective, T-86-37, Dec. 11, 1985; effective May 1, 1986; amended P-\_\_\_\_\_.)

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**28-35-181u. Registration of sealed source information.** (a) Each manufacturer or initial distributor of a sealed source or device containing a sealed source shall submit a request for a certificate of registration and shall complete an evaluation of radiation safety information about each manufacturer's or initial distributor's sealed source or device containing a sealed source.

(b) Each request for a certificate of registration of a sealed source or device containing a sealed source shall be submitted to the department and shall include information about the design, manufacture, prototype testing, quality control program, labeling, proposed uses, and leak testing.

Each request for a certificate of registration of a device containing a sealed source shall also include information about installation, service and maintenance, operating and safety instructions, potential health hazards, and minimization of danger to life and property.

(c) Each sealed source or device containing a sealed source shall be designed according to accepted industry standards or otherwise designed according to standards and criteria proposed by the manufacturer or distributor and accepted by the department.

(d) Each person submitting a request for review of safety information about the sealed source or device containing a sealed source shall manufacture and distribute the sealed source or device containing a sealed source in accordance with the following:

(1) The statements and representations, including quality control program, contained in the request for review; and

(2) the provisions of the certificate of registration.

(e) The authority to manufacture or initially distribute a sealed source or device

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containing a sealed source to specific licensees may be provided in the license without the issuance of a certificate of registration under either of the following conditions:

(1) The sources being manufactured or initially distributed are calibration and reference sources containing no more than either of the following:

- (A) 37 MBq (1 mCi), for beta- or gamma-emitting radionuclides; or
- (B) 0.37 MBq (10 $\mu$ Ci), for alpha-emitting radionuclides.

(2) Each intended recipient of the sealed source or device containing a sealed source meets all of the following conditions:

(A) For unregistered sources, the intended recipient is qualified by training and experience and has sufficient facilities and equipment to safely use and handle the requested quantity of radioactive material in any form.

(B) For registered sealed sources contained in unregistered devices, the intended recipient is qualified by training and experience and has sufficient facilities and equipment to safely use and handle the requested quantity of radioactive material in unshielded form, as specified in the intended recipient's license.

(C) At least one of the following conditions is met:

(i) Each intended recipient is licensed pursuant to K.A.R. 28-35-182a through 28-35-182d or comparable provisions of the NRC or agreement state.

(ii) Each intended recipient is authorized for research and development.

(iii) The sealed sources and devices containing sealed sources are to be built to the unique specifications of the particular recipient and contain no more than 740 GBq (20 Ci) of tritium or

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7.4 GBq (200 mCi) of any other radionuclide.

(f) Each holder of a certificate of registration shall provide the secretary or the secretary's designee with the opportunity to conduct additional reviews in accordance with this regulation as the secretary deems necessary to ensure compliance with these regulations. Any additional clarifying information necessary to conduct a review may be requested by the secretary. Each holder of a certificate of registration shall provide this information within 30 days of service of written notification from the secretary. (Authorized by and implementing K.S.A. 48-1607; effective P-\_\_\_\_\_.)

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**28-35-181v. Inactivation of certificates of registration for sealed sources and**

**devices.** (a)(1) Each holder of a certificate of registration that no longer manufacturers or initially transfers any sealed source or device covered by a certificate of registration issued by the department shall request inactivation of the certificate of registration. Each request shall be submitted to the department not later than two years after initial transfer of the sealed source or sealed sources or the device or devices covered by the certificate of registration.

(2) If a person issued a certificate of registration determines that the last initial transfer was made more than two years ago, that person shall request inactivation of the certificate of registration within 90 days of this determination and shall briefly describe the circumstances of the delay in the request to the department.

(b) If a license to distribute issued as specified in K.A.R. 28-35-181h through 28-35-181r is to be terminated in accordance with K.A.R. 28-35-191a or 28-35-205, the licensee shall request inactivation of the certificate of registration associated with the license to distribute before the department terminates the license. Each request for inactivation of a certificate of registration shall indicate that the license to distribute is being terminated and shall include the associated specific license number.

(c) A specific license to manufacture or initially transfer a sealed source or device containing a sealed source covered only by an inactivated certificate of registration shall no longer authorize a licensee to initially transfer the sealed source or device containing a sealed source for use.

(d) The servicing of a device containing a sealed source shall be performed in accordance with any conditions in the certificate of registration, including inactive certificates. (Authorized

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by and implementing K.S.A. 48-1607; effective P-\_\_\_\_\_.)

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**28-35-192e. Exemptions; gas and aerosol detectors containing radioactive material.**

(a) Except for persons ~~who~~ that manufacture, process, or produce gas and aerosol detectors containing radioactive material or ~~who~~ initially transfer these products for sale or distribution, each person ~~who~~ that acquires, receives, owns, possesses, uses, or transfers radioactive material in gas and aerosol detectors designated to protect life or property from fires and airborne hazards shall be exempt from ~~these regulations~~ the requirements for a license issued under K.A.R. 28-35-175a, except for the requirements of K.A.R. 28-35-700. Each detector shall have been manufactured, processed, produced, ~~imported,~~ or initially transferred in accordance with a specific license issued by the secretary pursuant to K.A.R. 28-35-181q or a license issued by the nuclear regulatory commission or by an agreement state pursuant to an equivalent regulation of the nuclear regulatory commission or the agreement state.

(b) Gas and aerosol detectors previously manufactured and distributed before November 30, 2007 to general licensees in accordance with a specific license issued by an agreement state shall be exempt ~~under~~ from the requirements of subsection (a) ~~if the device is labeled in accordance with the specific license authorizing distribution of the general licensed device and if the detectors meet the requirements of K.A.R. 28-35-181r.~~

(c) Each person ~~who desires~~ that wants to manufacture, process, or produce gas and aerosol detectors containing radioactive material, or to initially transfer these products for use pursuant to this regulation, shall apply for a license pursuant to K.A.R. 28-35-181q and a certificate of registration required by K.A.R. 28-35-181u. (Authorized by and implementing K.S.A. 48-1607; effective, T-86-37, Dec. 11, 1985; effective May 1, 1986; amended March 18, 2011; amended P-\_\_\_\_\_.)

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**28-35-192f. Exemptions; self-luminous products containing tritium, krypton-85 or promethium-147.** (a) ~~Except for persons who manufacture, process, or produce self-luminous products containing tritium, krypton-85, or promethium-147 and except as provided in subsection, (b) any person shall be exempt from these regulations to the extent that person acquires, possesses, uses, or transfers, tritium, krypton-85, or promethium-147 in self-luminous products manufactured, processed, produced, imported, or transferred in accordance with a specific license issued by the United States nuclear regulatory commission pursuant to Section 32.22 of Title 10 CFR 31, which authorizes the transfer of the product to persons who are exempt from regulatory requirements~~ Each person that wants to manufacture, process, produce, or initially transfer for sale or distribution self-luminous products containing tritium, krypton-85, or promethium-147 for use as specified in this subsection shall apply for the license required by K.A.R. 28-35-175a and the registration required by K.A.R. 28-35-181u.

(b) Each person not subject to subsection (a) that acquires, possesses, uses, or transfers tritium, krypton-85, or promethium-147 in self-luminous products manufactured, processed, produced, imported, or transferred in accordance with a specific license issued by the nuclear regulatory commission pursuant to 10 C.F.R. 32.22 shall be exempt from the requirements of this regulation.

(c) The exemption in subsection (a) (b) shall not apply to tritium, krypton-85, or promethium-147 used in toys, adornments, or similar items. (Authorized by and implementing K.S.A. 1984 Supp. 48-1607; effective, T-86-37, Dec. 11, 1985; effective May 1, 1986; amended P-\_\_\_\_\_.)

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**28-35-192h. Certain industrial devices.** (a) Except as specified in subsections (b) and (c), each person ~~who~~ that receives, possesses, uses, transfers, owns, or acquires any industrial device containing by-product material designed and manufactured for either of the following purposes shall be exempt from these regulations, except for the requirements of K.A.R. 28-35-700:

(1) Detecting, measuring, gauging, or controlling thickness, density, level, interface location, radiation, leakage, or qualitative or quantitative chemical composition; or

(2) producing an ionized atmosphere if the industrial device is manufactured, processed, produced, or initially transferred in accordance with a specific license issued pursuant to 10 C.F.R. 32.30 by the nuclear regulatory commission (~~NRC~~).

(b) Each person ~~who~~ that manufactures, processes, produces, or initially transfers for sale or distribution any industrial device containing by-product material designed and manufactured for either of the following purposes shall be excluded from the exemption in subsection (a):

(1) Detecting, measuring, gauging, or controlling thickness, density, level, interface location, radiation, leakage, or qualitative or quantitative chemical composition; or

(2) producing an ionized atmosphere.

(c) The exemption in subsection (a) shall exclude any source not incorporated into an industrial device, including calibration and reference sources.

(d) Each person ~~who~~ that manufactures, processes, produces, or initially transfers for sale or distribution any industrial device containing by-product material for use under subsection (a) shall apply for a license and a certificate of registration from the NRC. (Authorized by and implementing K.S.A. 48-1607; effective May 4, 2018; amended P-\_\_\_\_\_.)

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**28-35-195a. Intrastate transportation of radioactive materials.** (a) Each common or contract carrier shall be deemed to have been issued a general license to transport and store radioactive material in the regular course of its carriage for another, if the transportation and storage are performed in accordance with the regulations of the U.S. department of transportation and incorporated sections of 10 C.F.R. part 71 relating to the loading and storage of packages, shipping papers, placarding of a transporting vehicle, and incident reporting. Each person ~~who~~ that transports and stores radioactive material pursuant to the general license specified in this subsection shall be exempt from the requirements of parts 4 and 10 of these regulations.

(b) Each private carrier shall be deemed to have been issued a general license to transport radioactive material, if the transportation is performed in accordance with the regulations of the U.S. department of transportation and incorporated sections of 10 C.F.R. part 71 relating to the loading and storage of packages, shipping papers, placarding of a transporting vehicle, and incident reporting. Each person ~~who~~ that transports radioactive material under the general license issued in this subsection shall be exempt from the requirements of parts 4 and 10 of these regulations.

(c) Each physician shall be exempt from the requirements of subsection (b) ~~of this regulation~~ to the extent that the physician transports radioactive material for use in the practice of medicine.

(d) Each person deemed to have been issued a general license required by this regulation shall comply with part 15 of these regulations. (Authorized by and implementing K.S.A. 48-1607; effective, T-86-37, Dec. 11, 1985; effective May 1, 1986; amended Dec. 30, 2005; amended P-\_\_\_\_\_.)

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**28-35-196a. Preparation of radioactive material for transport.** (a) A licensee shall not deliver any radioactive material to a carrier for transport, or transport radioactive material as a private carrier, unless all of the following conditions are met:

(1) The licensee ~~complies~~ has complied with the applicable requirements of the regulations of the U.S. department of transportation and incorporated sections of 10 C.F.R. part 71 that are ~~appropriate~~ applicable to the mode of transport and that are related to the packing of radioactive material; and to the monitoring, marking, and labeling of ~~those packages;~~ packages containing radioactive material, including the exemptions specified in 10 C.F.R. part 71 subpart B.

(2) The licensee has established procedures for opening and closing packages in which radioactive material is transported to provide safety and to ~~assure~~ ensure that, ~~prior to~~ before the delivery to a carrier for transport, each package is properly closed for transport; ~~and~~ .

(3) ~~prior to delivery of a package to a carrier for transport;~~ The licensee has ~~assured~~ ensured that any special instructions needed to safely open ~~the~~ a package are sent to, or are available to, the consignee before delivery of the package to a carrier for transport.

(4) The licensee has ascertained, before the first use of any packaging for the shipment of licensed radioactive material, that the determinations specified in 10 C.F.R. 71.85(a) through (c) have been made.

(b) The requirements in subsection (a) ~~of this regulation~~ shall not apply to the transportation of licensed material; or to the delivery of licensed material to a carrier for transport, ~~when~~ if the transportation is subject to regulations of the U.S. postal service.

(Authorized by and implementing K.S.A. 1984-Supp. 48-1607; effective, T-86-37, Dec. 11,

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**28-35-227c. Records of radiation protection programs.** (a) Each licensee or registrant shall maintain records of the radiation protection program, including the following:

(1) The provisions of the program; and

(2) audits and other reviews of program content and implementation.

(b) The licensee or registrant shall retain the records required by ~~K.A.R. 28-35-227e(a)(1)~~ paragraph (a)(1) until the department terminates each pertinent licensee or registration requiring the record. ~~The licensee or registrant shall retain the records required by K.A.R. 28-35-227e(a)(2) for three years after the record is made.~~ (Authorized by and implementing K.S.A. 1993 Supp. 48-1607; effective Oct. 17, 1994; amended P-\_\_\_\_\_.)

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**28-35-231c. Transfer for disposal; manifests.** The provisions of 10 ~~CFR~~ C.F.R. 20.2006 as in effect on ~~October 1, 2007~~, including appendix G to 10 ~~CFR~~ C.F.R. part 20 as in effect on ~~November 16, 2005~~ dated January 1, 2019, are hereby adopted by reference.  
(Authorized by and implementing K.S.A. 48-1607; effective Dec. 30, 2005; amended March 18, 2011; amended P-\_\_\_\_\_.)

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**28-35-264. General requirements.** The provisions of 10 C.F.R. part 35, ~~as in effect on~~  
~~September 9, 2015~~ dated January 1, 2019, are hereby adopted by reference, with the changes  
specified in this regulation.

(a) For the purposes of part 6 of these regulations, ~~“byproduct by-product material”~~ shall  
mean all radioactive material regulated by the department.

(b) All reports required by this regulation shall be submitted to the department.

(c) The following sections shall be deleted:

(1) 35.1, “purpose and scope”;

(2) 35.2, “definitions,” except that the definitions of the following terms shall be retained:

(A) “Authorized medical physicist”;

(B) “authorized nuclear pharmacist”;

(C) “authorized user”;

(D) “medical event”;

(E) “prescribed dose”; and

(F) “radiation safety officer”;

(3) 35.8, “information collection requirements: OMB approval”;

(4) 35.18, “license issuance”;

(5) 35.19, “specific exemptions”;

(6) 35.26(a)(1), “radiation protection program changes”;

(7) 35.57(a)(4), “training for experienced radiation safety officer, teletherapy or medical  
physicist, authorized medical physicist, authorized user, nuclear pharmacist, and authorized  
nuclear pharmacist”;

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(8) 35.4001, “violations”; and

(8) (9) 35.4002, “criminal penalties.”

(d) Wherever the following C.F.R. references occur within 10 C.F.R. part 35, these references shall be replaced with the specified references to regulations and parts in this article of the department’s regulations:

(1) “10 CFR 19.12” shall be replaced with “K.A.R. 28-35-333, ‘instructions to workers.’ ”

(2) “10 CFR part 20” shall be replaced with “part 4, ‘standards for protection against radiation.’ ”

(3) “10 CFR 20.1101” shall be replaced with “K.A.R. 28-35-211d, ‘radiation protection programs.’ ”

(4) “10 CFR 20.1301(a)(1) and 20.1301(c)” shall be replaced with “K.A.R. 28-35-214a.”

(5) “10 CFR 20.1501” shall be replaced with “K.A.R. 28-35-217b.”

(6) “10 CFR part 30” shall be replaced with “part 3, ‘licensing of sources of radiation.’ ”

(7) “10 CFR 32.72” shall be replaced with “K.A.R. 28-35-181m, ‘specific licenses to manufacture, prepare, and or distribute radiopharmaceuticals containing radioactive material for medical use ~~under group licenses~~,’ and K.A.R. 28-35-181n, ‘specific licenses to manufacture and distribute generators or reagent kits for preparation of radiopharmaceuticals containing radioactive material.’ ”

(8) “10 CFR 32.74” shall be replaced with “K.A.R. 28-35-181o, ‘specific licenses to manufacture and distribute sources and devices for use as a calibration, transmission, or

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reference source; or for certain medical uses.’ ”

(9) “10 CFR 33.13” shall be replaced with “K.A.R. 28-35-182b, ‘qualifications for a type A specific license of broad scope.’ ”

(e) Wherever the following terms occur within 10 C.F.R. part 35, these terms shall be replaced with “department”:

(1) “Commission,” with the exception of the phrase “Commission or Agreement State”;

(2) “NRC ~~operation~~ operations center”; and

(3) “NRC regional office.”; and

(4) “NRC.”

(f) The following changes shall be made to the sections specified:

(1) 35.6(b)(1) and (c)(1) shall be replaced with the following text:

“Obtain review and approval of the research as specified in 45 CFR 46.111, ‘criteria for IRB approval of research’; and”.

(2) 35.6(b)(2) and (c)(2) shall be replaced with the following text:

“Obtain informed consent from the human research subject as specified in 45 CFR 46.116, ‘general requirements for informed consent.’ ”

(3) 35.10, ~~subsection~~ (a) shall be deleted.

(4) In 35.10(d), the date “October 24, 2002” shall be replaced with “the effective date of these regulations.”

(5) 35.12(b)(1) shall be replaced with the following text: “submitting a form specified by the department that includes the facility diagram, equipment, and training and experience

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qualifications of the radiation safety officer, authorized users, authorized physicists, and authorized pharmacists.”

(6) 35.12(c)(1)(i) shall be replaced with the following text: “a form specified by the department that includes the facility diagram, equipment, and training and experience qualifications of the radiation safety officer, authorized users, authorized physicists, and authorized pharmacists.”

(7) 35.12(c)(1)(ii) shall be replaced with the following text: “a letter containing all information required by the form in (i); and”.

(8) In 35.57(a)(1) and (b)(1), the date “~~October 24, 2002~~” “January 14, 2019” shall be replaced with “the effective date of these regulations.”

(8) (9) In 35.57(a)(2), (a)(3), and (b)(2), the date “~~April 29, 2005~~” “October 24, 2005” shall be replaced with “the effective date of these regulations.”

(9) (10) In 35.432(a), the date “October 24, 2002” shall be replaced with “the effective date of these regulations.”

(10) (11) In 35.3045, the footnote shall be deleted, and in subsection (a) the words “or any radiation-producing device” shall be added before the words “results in.”

(11) (12) 35.3047(d) shall be replaced with the following text: “The licensee shall submit a written report to the department within 15 days after discovery of a dose to the embryo or fetus, or nursing child that requires a report in paragraphs (a) or (b) in this section.”

(12) (13) In 35.3067, the phrase “with the department” shall be inserted after the word “report” in the first sentence, and the second sentence shall be deleted. (Authorized by and

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implementing K.S.A. 48-1607; effective Dec. 30, 2005; amended March 18, 2011; amended May 4, 2018; amended P-\_\_\_\_\_.)

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**28-35-282a. Inspection and maintenance of radiation machines, radiographic exposure devices, transport and storage containers, associated equipment, source changers, and survey instruments.** (a) Each licensee or registrant shall perform visual and operability checks on the survey meters, radiation machines, radiographic exposure devices, each transport and storage container, and any associated equipment and source changers before each day's use, or each work shift, to ensure that all of the following conditions are met:

(1) The equipment is in good working condition.

(2) The sources are shielded.

(3) The required labeling is present.

(b) Survey instrument operability shall be performed by using dedicated check sources or other appropriate means.

(c) If equipment problems are found, the equipment shall be removed from service until repaired.

(d) Each licensee or registrant shall have written procedures for and shall perform inspections and routine maintenance on the radiation machines, radiographic exposure devices, source changers, associated equipment, transport and storage containers, and survey instruments. The inspections and maintenance shall occur at least every three months or before the next use to ensure proper functioning of components important to safety. Each replacement component shall meet the design specifications of the manufacturer. If equipment problems are found, the equipment shall be removed from service until repaired.

(e) ~~The~~ Each licensee's inspection and maintenance program shall include procedures to ensure that type B packages are shipped and maintained in accordance with the certificate of

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compliance or other type of approval.

(f) Each licensee or registrant shall maintain records of inspection, equipment problems, and any maintenance performed under this regulation for three years. These records shall ~~indicate~~ specify the following:

(1) The date of the check or inspection;

(2) the name of the inspector;

(3) the equipment modified;

(4) any problems found; and

(5) any repairs needed and any maintenance and equipment problems found. (Authorized by and implementing K.S.A. 48-1607; effective Dec. 30, 2005; amended P-\_\_\_\_\_.)

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**28-35-291. Performance requirements for radiography equipment.** (a) Each radiographic exposure device and all associated equipment shall have been certified by the NRC as compliant with the requirements specified in "radiological safety for design and construction of apparatus for gamma radiography," published by the American national standards institute as NBS handbook 136, issued January 1981, ANSI N432-1980 standards. As an alternative, any licensee or applicant may submit an engineering analysis demonstrating that testing previously performed on similar individual radiography components is adequate to support a finding that the previous testing is an acceptable substitute for that described in the N432-1980 standards.

(b) In addition to the requirements specified in subsection (a), ~~the~~ each licensee shall ensure that each radiographic exposure device and all associated equipment meet the following requirements- :

(1) Each user of a radiographic exposure device shall attach to the device a durable, legible, clearly visible label bearing the following information:

- (A) The chemical symbol and mass number of the radionuclide in the device;
- (B) the radioactive activity level and the date on which this activity was last measured;
- (C) the model number and serial number of the sealed source;
- (D) the manufacturer of the sealed source; and
- (E) the licensee's name, address, and telephone number.

(2) Each radiographic exposure device intended for use as a type B transport container shall have been certified by the NRC as compliant with the applicable requirements of 10 C.F.R. 71.51.

(3) The licensee shall not modify any radiographic exposure device or associated

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equipment in a manner that compromises the design safety features of the system.

(c) In addition to the requirements specified in subsections (a) and (b), the licensee shall ensure that each radiographic exposure device and the associated equipment that allows the source to be moved out of the device for routine operation meet the following requirements: :

(1) The coupling between the source assembly and the control cable shall be designed so that the source assembly cannot become disconnected if cranked outside the guide tube. The coupling shall be designed to prevent an unintentional disconnection under normal conditions and reasonably foreseeable abnormal conditions.

(2) The radiographic exposure device shall automatically secure the source assembly when the source assembly is cranked back into the fully shielded position in the radiographic exposure device. A deliberate operation on the radiographic exposure device shall be required to release the source assembly.

(3) The outlet fitting, lock box, and drive cable fittings on each radiographic exposure device shall be equipped with safety plugs or covers, which shall be installed during storage and transportation to protect the source assembly from water, mud, sand, and other foreign matter.

(4) Each sealed source or source assembly shall have attached to it or engraved on it a durable, legible, visible label with these words: "DANGER RADIOACTIVE." The label shall not interfere with the safe operation of the radiographic exposure device or the associated equipment.

(5) Each sealed source that is not fastened to, or contained in, a radiographic exposure device shall have a durable tag permanently attached to the sealed source. The tag shall measure

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at least one square inch and shall bear the radiation symbol described in K.A.R. 28-35-219a and, at a minimum, the following instructions: "Danger—Radioactive Material—Do Not Handle—Notify Civil Authorities If Found."

(6) The guide tube shall have passed the crushing tests for the control tube as specified in ANSI N432-1980 standards and a kinking resistance test that closely approximates the kinking forces likely to be encountered during use.

(7) Guide tubes shall be used when moving the source out of the radiographic exposure device.

(8) An exposure head or similar device shall be used to prevent the source assembly from passing out of the end of the guide tube during radiographic operations.

(9) The guide tube exposure head connection shall be able to withstand the tensile test for control units specified in ANSI N432-1980 standards.

(10) Each source changer shall provide a system for ensuring that the source ~~can not~~ cannot accidentally be withdrawn from the changer when connecting or disconnecting the drive cable to or from a source assembly.

(d) Each licensee shall ensure that all newly manufactured radiographic exposure devices and the associated equipment acquired after January 10, 1995 meet the requirements of this regulation.

(e) Each licensee shall ensure that all radiographic exposure devices and the associated equipment used by the licensee after January 10, 1995 meet the requirements of this regulation.

(f) Any licensee may use equipment in industrial radiographic operations that does not

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comply with section 8.9.2(c) of the endurance test in ANSI N432-1980 standards, if prototype equipment has been tested using a torque that an individual using the radiography equipment can realistically exert on the lever or crankshaft of the drive mechanism. (Authorized by and implementing K.S.A. 48-1607; effective Nov. 1, 1996; amended Dec. 30, 2005; amended P-\_\_\_\_\_.)

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**28-35-450. General requirements.** The provisions of “part X: therapeutic radiation machines” in volume 1 of the “suggested state regulations for control of radiation,” including appendix A, published by the conference of radiation control program directors, inc. and dated ~~February 2005~~ March 2009, are hereby adopted by reference, with the changes specified in this regulation.

(a) Sec. X.2, “definitions,” shall be deleted.

(b) ~~Sec. X.3(d)(vi) shall be deleted.~~

(e) Wherever the following phrases and references occur in part X, these phrases and references shall be replaced with the specified phrases and references to regulations and parts in this article of the department’s regulations:

(1) “Agency” shall be replaced with “department.”

(2) “[INSERT EFFECTIVE DATE OF THESE REGULATIONS]” shall be replaced with “the effective date of these regulations.”

~~(3) “G.14” shall be replaced with “part 6.”~~

~~(4)~~ (c) The following phrases in part X shall be replaced with the phrase “part 4”:

(1) In sec. X.3(i), “Parts D.1201, ~~D.1205~~ and D.1502, and D.1204”;

(2) in sec. X.4(a)(i)(1), “Part D.1201a.”;

(3) in sec. X.4(a)(i)(2), “Parts D.1301a. and D.1301b”;

(4) in sec. X.4(b), (b)(i), and (b)(iv), “Parts D.1301a. and D.1301b.”;

(5) in sec. X.4(b)(iv), “Part D.1301c.”;

(6) in sec. X.6(r)(vi), “Part D.1201”;

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(7) in sec. X.7(q)(vii), “Parts D.1301a. and D.1301b.”;

(8) in sec. X.9(a), “Parts D.1201 and D.1301”; and

(9) in sec. X.11(i)(iv), “D.1201”; and

(8) (10) in appendix A, sec. II(C), “Part D.1201.”

(e) (d) In sec. X.3(e), paragraph (i) shall be replaced with the following text: “Individuals operating a therapeutic radiation machine for healing arts purposes shall meet the requirements specified in the radiologic technologists practice act and shall have satisfactorily completed an education program in radiation therapy that meets the criteria specified in K.A.R. 100-73-3.”  
(Authorized by and implementing K.S.A. 48-1607; effective Dec. 30, 2005; amended July 27, 2007; amended P-\_\_\_\_\_.)

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**28-35-500. General license: NRC-approved packages.** (a) A general license shall be deemed to have been issued to any licensee to transport, or to deliver to a carrier for transport, any licensed or registered material in a package for which a license, certificate of compliance (~~CeC~~), or other approval has been issued by the NRC.

(b) Each general license specified in subsection (a) shall apply only to a licensee who has a quality assurance program approved by the ~~NRC~~ department.

(c) Each general license specified in subsection (a) shall apply only to a licensee who meets the following requirements:

(1) ~~Has~~ Possesses a copy of the specific license, certificate of compliance, or other approval by the NRC for the package and has the drawings and any other documents referenced in the approval relating to the use and maintenance of the package and to the actions to be taken before shipment;

(2) complies with the terms and conditions of the license, certificate of compliance, or other approval, as applicable, and with the applicable requirements of ~~this part~~ 15 of these regulations; and

(3) ~~has registered~~ registers with the NRC before the licensee's first use of the package according to the methods described in 10 C.F.R. 71.17(c)(3), dated January 1, 2020, which is hereby adopted by reference.

(d) Each general license specified in subsection (a) shall apply only if the package approval authorizes the use of the package under this general license.

(e) Each general licensee specified in subsection (a) shall meet the requirements of K.A.R. 28-35-501 when using any type B or fissile material package approved by the NRC before April 1, 1996. (Authorized by and implementing K.S.A. 48-1607; effective Dec. 30, 2005; amended

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**28-35-500a. General license: use of foreign-approved package.** (a)(1) A general license shall be deemed to have been issued to any licensee to transport, or to deliver to a carrier for transport, any licensed or registered material in a package with a design approved as documented by a foreign national competent authority certificate that has been revalidated by the U.S. department of transportation as meeting the applicable requirements of 49 C.F.R. 171.23.

(2) Except as otherwise provided in part 15 of these regulations, the general license shall be valid only for a licensee who has a quality assurance program approved by the NRC or the department as meeting the applicable provisions of K.A.R. 28-35-505.

(b) Each general license issued under subsection (a) shall apply only to shipments made to or from locations outside the United States.

(c) Each licensee issued a general license under subsection (a) shall meet the following requirements:

(1) Have a copy of the specific license, certificate of compliance, or other approval by the NRC for the package and have the drawings and any other documents referenced in the approval relating to the use and maintenance of the package and to the actions required before shipment; and

(2) comply with the terms and conditions of the license, certificate of compliance, or other approval, as applicable, and with the applicable requirements of part 15 of these regulations.

(Authorized by and implementing K.S.A. 48-1607; effective P-\_\_\_\_\_.)

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**28-35-504. Advance notification of shipment of certain types of licensed or registered material.** (a)(1) As specified in subsections (b), (c), and (d), each licensee shall provide advance notification to the governor or the governor's designee of each state of each shipment of licensed or registered material through or across the boundary of that ~~governor's~~ state. The licensee shall provide this advance notification before transporting, or delivering to a carrier for transport, any licensed or registered material outside the confines of the licensee's ~~facility~~ plant or other place of use or storage.

(2) As specified in subsections (b), (c), and (d), each licensee shall provide advance notification to the Indian tribal official ~~or tribal official~~ of participating tribes referenced in subsection (c), or the official's designee, of the shipment of licensed material within or across the boundary of the tribe's reservation before the transport or delivery to a carrier for transport of licensed material outside the confines of the licensee's plant or other place of use or storage.

(b)(1) The advance notification specified in subsection (a) shall be required for each shipment of irradiated reactor fuel containing 100 grams or less in net weight of irradiated fuel, exclusive of cladding and any other structural or packaging material, that has a total external radiation dose rate in excess of 100 rems per hour at a distance of three feet from any accessible surface without intervening shielding.

(2) The advance notification specified in subsection (a) shall also be required for each shipment of licensed or registered material, other than irradiated fuel, meeting all of the following conditions:

(A) The licensed or registered material is required to be shipped in a type B package for transportation as specified in ~~this part~~ 15 of these regulations.

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(B) The licensed or registered material is being transported to or across a state boundary en route to a disposal facility or to a collection point for transport to a disposal facility.

(C) The quantity of licensed or registered material in a single package exceeds the smaller of the following:

(i) 3,000 times the  $A_1$  value of the radionuclides as specified in 10 C.F.R. part 71, appendix A, which is adopted by reference in K.A.R. 28-35-221b, for special form radioactive material or 3,000 times the  $A_2$  value of the radionuclides as specified in ~~10 C.F.R. part 71, appendix A, which is adopted by reference~~ in K.A.R. 28-35-221b for normal form radioactive material; and

(ii) 1,000 TBq (27,000 Ci).

(c) The notification specified in subsection (b) shall meet the following requirements:

(1) The notification shall be submitted, in writing, to the office of each appropriate governor or governor's designee and each appropriate Indian tribal official ~~and to the director of the division of nuclear security in the office of nuclear security and incident response~~ or tribal official's designee and to the director of the office of nuclear security and incident response.

(2) Each notification delivered by mail shall be postmarked at least seven days before the beginning of the seven-day period during which departure of the shipment is estimated by the licensee to occur.

(3) Each notification delivered by any means other than mail shall reach the office of each governor or governor's designee and each appropriate Indian tribal official or tribal official's designee at least four days before the beginning of the seven-day period during which departure of the shipment is estimated by the licensee to occur.

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(4) Each licensee shall retain a copy of the notification as a record for three years.

(d) Each advance notification of any shipment of irradiated reactor fuel or nuclear waste shall contain the following information:

(1) The name, address, and telephone number of the shipper, carrier, and receiver of the irradiated reactor fuel or nuclear waste shipment;

(2) a description of the irradiated reactor fuel or nuclear waste contained in the shipment, as specified in the regulations of the ~~United States~~ U.S. department of transportation (~~USDOT~~) in 49 C.F.R. 172.202 and 172.203(d), dated October 1, 2019, which are hereby adopted by reference;

(3) a shipment schedule, which shall include the following information:

(A) The point of origin of the shipment and a specification of the seven-day period during which departure of the shipment is estimated by the licensee to occur;

(B) a specification of the seven-day period during which arrival of the shipment at the state boundaries or tribal reservation boundaries is estimated by the licensee to occur; and

(C) the destination of the shipment and a specification of the seven-day period during which arrival of the shipment at the destination is estimated by the licensee to occur; and

(4) the name of a contact person, including a telephone number, for current shipment information.

(e) If any licensee finds out that the shipment schedule previously furnished to any governor, governor's designee, ~~or Indian tribal official,~~ or tribal official's designee in accordance with this regulation will not be met, that licensee shall perform the following:

(1) Telephone a responsible individual in the office of the governor or governor's

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designee or the Indian tribal official or the tribal official's designee as soon as practical after the licensee has found out that the shipment schedule will not be met and inform that individual of the revised schedule; and

(2) maintain a record of the name of the responsible individual contacted and the date of this contact for three years.

(f) Each licensee who cancels an irradiated reactor fuel or nuclear waste shipment for which advance notification has been sent shall send a cancellation notice to the governor of each state or the governor's designee or to the Indian tribal official or to the tribal official's designee who was previously notified and to the director of the ~~division of nuclear security~~ in the office of nuclear security and incident response. The licensee shall state in the notice that the notice is a cancellation and shall identify the advance notification that is being canceled. The licensee shall retain a copy of the notice as a record for three years. (Authorized by and implementing K.S.A. 48-1607; effective Dec. 30, 2005; amended May 4, 2018; amended P-\_\_\_\_\_.)

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**28-35-504a. Records.** (a) Each licensee shall maintain a record of each shipment of licensed material not exempt under 10 C.F.R. 71.14 for three years after shipment. Each record shall meet the following requirements:

- (1) Identify the package by model number and serial number;
- (2) verify that there are no defects in the packaging impacting the integrity, functionality, or safety of the package as shipped;
- (3) specify the volume and identification of coolant;
- (4) specify the type and quantity of licensed material in each package;
- (5) specify the total quantity of each shipment;
- (6) for each item of irradiated fissile material, meet the following requirements:
  - (A) Identify the package by model number and serial number;
  - (B) document the irradiation and decay history to the extent appropriate to demonstrate that the nuclear and thermal characteristics of the irradiated fissile material complies with license conditions; and
  - (C) document any abnormal or unusual condition relevant to radiation safety;
- (7) document the date of the shipment;
- (8) for fissile packages and for type B packages, document any special controls exercised;
- (9) specify the name and address of the transferee;
- (10) specify the address to which the shipment was made; and
- (11) document the results of the determinations required by 10 C.F.R. 71.87 and by the conditions of the package approval.

(b) Each licensee, certificate holder, and applicant for a certificate of compliance shall

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make all records required by part 15 of these regulations available to the department for inspection upon reasonable notice. Each record shall be valid only if stamped, initialed, or signed, if dated by authorized personnel, or if otherwise authenticated.

(c) Each licensee, certificate holder, and applicant for a certificate of compliance shall maintain written records as evidence of the quality of packaging. The records shall include the following:

- (1) Results of the determinations required by 10 C.F.R. 71.85;
- (2) design, fabrication, and assembly records;
- (3) results of reviews, inspections, tests, audits, monitoring work performance, and materials analyses; and
- (4) results of maintenance, modification, and repair activities.

(d) The inspection, test, and audit records maintained by the licensee, certificate holder, and applicant for a certificate of compliance shall include the following:

- (1) Identification of the inspector or data recorder;
- (2) the type of observation;
- (3) the results;
- (4) the acceptability; and
- (5) the action taken in connection with any deficiencies noted.

(e) The records required by subsections (c) and (d) shall be retained for three years after the life of the packaging to which the records apply. (Authorized by and implementing

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**28-35-505. Quality assurance requirements.** ~~Each program for transport container inspection and maintenance that is limited to radiographic exposure devices, source changers, or any package transporting these devices or changers and that meets the requirements of K.A.R. 28-35-282a or equivalent NRC or agreement state requirements shall be deemed to meet the requirement specified in K.A.R. 28-35-500(b)~~ The provisions of 10 C.F.R. part 71, subpart H, dated January 1, 2019, are hereby adopted by reference, with the changes specified in this regulation.

(a) The following sections shall be deleted:

(1) 71.101(c)(2), (d), and (e);

(2) 71.107;

(3) 71.109;

(4) 71.111;

(5) 71.113;

(6) 71.115;

(7) 71.117;

(8) 71.119;

(9) 71.121;

(10) 71.123; and

(11) 71.125.

(b) The changes specified in this subsection shall be made wherever the following text occurs within the portions of 10 C.F.R. part 71 adopted in this regulation:

(1) “ATTN: Document Control Desk, Director, Division of Fuel Management, Office of

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Nuclear Material Safety and Safeguards” shall be replaced with “the department.”

(2) “NRC Form 3” shall be replaced with “department form RH-3.”

(3) “Subpart H of this part” and “§§71.010 through 71.137” shall be replaced with “K.A.R. 28-35-505.”

(4) “This chapter” shall be replaced with “10 C.F.R.”

(c) Wherever the following terms occur within the portions of 10 C.F.R. part 71 adopted in this regulation, these terms shall be replaced with “department”:

(1) “Administrator of the appropriate Regional Office”;

(2) “commission”;

(3) “NRC”;

(4) “Nuclear Regulatory Commission”; and

(5) “United States Nuclear Regulatory Commission.”

(d) The following changes shall be made to the sections specified:

(1) In 10 C.F.R. 71.101(a), the following sentence shall be deleted: “Each certificate holder and applicant for a package approval is responsible for satisfying the quality assurance requirements that apply to design, fabrication, testing, and modification of packaging subject to this subpart.”

(2) In 10 C.F.R. 71.101(f), the sentence “The licensee, certificate holder, and applicant for a CoC shall identify the program by date of submittal to the Commission, Docket Number, and date of Commission approval” and the phrase “in accordance with §71.1” shall be deleted.

(3) 10 C.F.R. 71.101(g) shall be replaced by the following text:

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“Each program for transport container inspection and maintenance that is limited to radiographic exposure devices, source changers, or any package transporting these devices or changers and that meets the requirements of K.A.R. 28-35-282a or equivalent NRC or agreement state requirements shall be deemed to meet the requirement specified in K.A.R. 28-35-500(b).”

(e) The terms “certificate of compliance,” “certificate holder,” and “applicant” shall apply to the NRC as the sole authority for issuing a package certificate of compliance.

(f) Each submittal required by this regulation shall be submitted to the department, with the exception of a certificate of compliance. (Authorized by and implementing K.S.A. 48-1607; effective Dec. 30, 2005; amended P-\_\_\_\_\_.)

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**28-35-700. General requirements.** The provisions of 10 C.F.R. part 37, ~~78 fed. reg. 17007-~~  
~~17020 (2013), as in effect on May 20, 2013~~ dated January 1, 2019, are hereby adopted by  
reference, with the changes specified in this regulation.

(a) The following sections or portions of sections in 10 C.F.R. part 37 shall be deleted:

- (1) 37.1;
- (2) 37.3;
- (3) 37.7;
- (4) 37.9;
- (5) 37.11(a) and (b);
- (6) 37.13;
- (7) ~~37.43(d)~~(9);
- ~~(8)~~ in 37.81(g), the third sentence;
- ~~(9)~~ (8) 37.105;
- ~~(10)~~ (9) 37.107; and
- ~~(11)~~ (10) 37.109.

(b) In 10 C.F.R. 37.5, the following terms and the definition of each of these  
terms shall be deleted:

- (1) “Act”;
- (2) “agreement state”;
- (3) “becquerel”;
- (4) “byproduct material”;
- (5) “commission”;

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- (6) “curie”;
- (7) “government agency”;
- (8) “license”;
- (9) “lost or missing licensed material”;
- (10) “person”;
- (11) “state”; and
- (12) “United States.”

(c) Wherever the following words terms and phrases occur within the portions of 10 C.F.R. part 37 adopted in this regulation, these words terms and phrases shall be replaced with “department”:

- (1) “Appropriate NRC regional office listed in §30.6(a)(2) of this chapter”;
- (2) “commission,” except secs. 37.5, 37.27(a) and (c), 37.29(a), and 37.71;
- (3) “NRC,” except secs. ~~37.25(b)(2)~~, 37.25(c), 37.27(c), 37.29(a), and 37.71;
- (4) “NRC regional office specified in §30.6 of this chapter”;
- (5) “NRC’s Operations Center”; and
- (6) “NRC’s Operations Center (301-816-5100).”

(d) The following changes shall be made wherever the following text occurs within the portions of 10 C.F.R. part 37 adopted in this regulation:

- (1) “Part 73 of this chapter” shall be replaced with “10 C.F.R. Part 73.”
- (2) “71.97(b) of this chapter” and “71.97 of this chapter” shall be replaced with “K.A.R. 28-35-504(b).”

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(3) "Governor's designee" shall be replaced with "division of emergency management of the office of the adjutant general." (Authorized by and implementing K.S.A. 48-1607; effective May 4, 2018; amended P-\_\_\_\_\_.)

APPROVED

DEC 10 2020

DIVISION OF THE BUDGET

APPROVED

DEC 21 2020

DEPT. OF ADMINISTRATION

APPROVED

MAY 11 2021

ATTORNEY GENERAL